IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION

MDL No. 3014

Master Docket: No. 21-mc-1230-JFC

This Document Relates to:

Consolidated Second Amended Class Action Complaint for Medical Monitoring (ECF No. 815)

PHILIPS RS NORTH AMERICA LLC'S SUPPLEMENTAL BRIEF IN SUPPORT OF THE MOTION TO DISMISS THE SECOND AMENDED CLASS ACTION COMPLAINT FOR MEDICAL MONITORING

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Philips RS North America LLC ("Respironics") respectfully submits this supplemental brief in support of its motion to dismiss Plaintiffs' Second Amended Class Action Complaint for Medical Monitoring ("MMSAC") (ECF No. 815).

I. PRELIMINARY STATEMENT

The District Court has remanded Respironics's Motion to Dismiss the MMSAC to the Special Master to issue a revised report and recommendation consistent with the District Court's guidance. ECF No. 2522. On remand, the District Court has asked for (i) "a thorough survey" of relevant state law "to determine whether a stand-alone claim is plausibly stated for medical monitoring or if any other claim is plausibly stated for which medical monitoring may be obtained as a form of relief," and (ii) "a roadmap for a ruling on the motion to dismiss which identifies, for each count and each state, the claims that will survive." ECF No. 2521("Remand Op.") at 5, 18. The District Court posed certain other claim-specific questions to aid in these tasks. *Id.* at 19.

As shown below, very few of Plaintiffs' claims should survive, primarily because most states require Plaintiffs to plead a manifest physical injury to state a claim for medical monitoring relief, and Plaintiffs' allegations of latent "subcellular change" and economic losses do not suffice. A proposed "roadmap for a ruling on the motion to dismiss" is provided at the conclusion of this supplemental memorandum showing those claims, for each count and state, that should be dismissed under the reasoning of the Special Master's September 28, 2023 report and recommendation (ECF No. 2273) (the "R&R") and consistent with the District Court's guidance.

• Negligence and Strict Liability Claims (Counts I-II, V-IX)¹

- The District Court has asked whether "the tort claims for each state" include, "as an element of the prima facie case, injury[,]" and "whether economic harm or subcellular harm will satisfy that element." Remand Op. at 19.
- The traditional rule in all states requires plaintiffs to plead, as an element of negligence and strict products liability claims, that the plaintiff has suffered a present, manifest physical injury. Economic loss, by definition, is not a physical injury. Allegations of economic losses not arising from a manifest physical injury do not suffice to state a claim for negligence or products liability for which relief can be granted in states that adhere to the traditional rule.
- The parties agree that New Hampshire, North Carolina, and Delaware ("Undisputed Traditional Rule Jurisdictions") adhere to the traditional rule and require plaintiffs to plead a manifest physical injury to state a cause of action.
- The parties likewise agree that California, the District of Columbia, Florida, Maryland, Massachusetts, Missouri, Nevada, Pennsylvania, Utah, Vermont, and West Virginia ("Undisputed Minority Rule Jurisdictions") deviate from the traditional rule and permit plaintiffs to allege claims seeking medical monitoring relief without requiring allegations of manifest physical injury.

¹ These claims are, respectively: Negligence, Negligence *Per Se*, Products Liability Design-Defect, Negligent Design, Strict Liability Failure to Warn, Negligent Failure to Warn, and Negligent Recall.

- For all of the remaining relevant jurisdictions (the "Disputed Jurisdictions"),² the Court must make a prediction under *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938) to assess whether the highest court of each state would deviate from the traditional rule. The R&R correctly stated that Third Circuit precedent requires courts to opt against expanding liability under state law unless, based on reliable authorities, a "clear indication" exists that that the jurisdiction's highest court would do so. The District Court concurred. (Remand Op. at 15).
- The R&R correctly found that twenty-seven of the Disputed Jurisdictions would adhere to the traditional rule and require plaintiffs to allege a manifest physical injury to state a negligence or products liability claim for which relief can be granted. As shown in the detailed state law survey below, and consistent with the District Court's guidance in the Remand Opinion, on remand Tennessee should also be added to the list of Disputed Jurisdictions in which plaintiffs must allege a manifest physical injury in order to state a negligence or products liability claim.
- Plaintiffs here have not alleged a manifest physical injury and their claims must be dismissed under the laws of states that adhere to the traditional rule. Plaintiffs allege in conclusory fashion that they have experienced latent "subcellular injury" or "other physiological change" as a result of using the recalled devices. *E.g.*, MMSAC ¶ 56. *No court, in any state*, has *ever held* that latent "subcellular injury" or "physiological change" is a "manifest physical injury" for purposes of pleading a tort claim.

² The Disputed Jurisdictions are Arizona, Arkansas, Colorado, Connecticut, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Minnesota, Montana, Nebraska, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Carolina, Tennessee, Texas, Virginia, and Washington.

Decause *Erie* permits only the conclusion that the Undisputed Minority Rule jurisdictions deviate from the manifest physical injury pleading requirement for negligence and products liability claims, Plaintiffs' negligence and products liability claims asserted under the laws of the Disputed Jurisdictions and the Undisputed Traditional Rule Jurisdictions (Counts I-II, V-VIII) should be dismissed for failure to allege manifest physical injury.

• Fraud (Count XIII) and Negligent Misrepresentation (Count III)

o Manifest physical injury is not traditionally an element of claims alleging fraud or negligent misrepresentation. However, Plaintiffs' allegations in support of their fraud and negligent misrepresentation claims are materially indistinguishable from those in the Master Personal Injury Amended Complaint ("PIAC"). Accordingly, as the District Court ruled with respect to the PIAC, Plaintiffs' fraud claim here fails Rule 9(b)'s particularity requirement and should be dismissed in its entirety. Plaintiffs' negligent misrepresentation claim also fails in those jurisdictions identified in the District Court's Order granting in part Respironics' Motion to Dismiss the PIAC, for the same reasons articulated in that Order and in the Special Master's Report and Recommendation on Respironics' Motion to Dismiss the PIAC. ECF No. 2471; ECF No. 2271.

• Stand-Alone Medical Monitoring Claim (Count IV)

The District Court asked the Special Master to "identify which state subclasses remain" for Plaintiffs' stand-alone medical monitoring claim, and to determine "whether the relevant state law requires a physical harm; and if so, whether subcellular change is sufficient." Remand Op. at 19.

- In the minority of jurisdictions that permit stand-alone medical monitoring claims,
 allegations of manifest physical injury are not necessary to state a claim.
- Plaintiffs' stand-alone medical monitoring claims asserted under the laws of Connecticut, Colorado, Delaware, Montana, and New Hampshire should be dismissed, because those states have not expressly recognized such a claim, and under an *Erie* analysis the highest courts of these states have given no "clear indication" that they would do so.
- Plaintiffs' stand-alone medical monitoring claim, therefore, survives only as asserted under the laws of the District of Columbia, Florida, Massachusetts, Pennsylvania, Utah, and West Virginia, where such a cause of action is recognized.

• Products Liability Acts (Count XIV)

- For the Products Liability Acts claim, the District Court directed the Special Master to "examine the statutory language and applicable caselaw to determine whether injury or harm is a necessary element of the claim," and "whether subcellular change would be sufficient to plead a physical injury." Remand Op. at 19.
- O Plaintiffs assert claims under the Products Liability Acts of seven states: Connecticut, Indiana, Kansas, New Jersey, Ohio, Tennessee, and Washington. MMSAC ¶¶ 701-735. These claims should be dismissed because, properly construed, each state's act requires Plaintiffs to allege a manifest physical injury to state a claim.
- O The states' Products Liability Acts are derived, to greater or lesser extents, from the Model Uniform Product Liability Act, and the adopted provisions relevant here all use similar language and structure that should be afforded a consistent interpretation. The Supreme Court of New Jersey held in *Sinclair v. Merck & Co.*, 948 A.2d 587 (N.J.

2008), that the New Jersey Products Liability Act requires plaintiffs to allege a manifest physical injury to recover medical monitoring damages. The statutes in Connecticut, Indiana, Kansas, Ohio, and Tennessee use the same text to define the harm that is actionable under the law, and appellate decisions in those states concur with *Sinclair*.

- The Washington Products Liability Act uses a slight variation of the model text, but the variation does not compel a different result because Washington adheres to the manifest physical injury requirement for all tort claims, including products liability claims, and Washington's highest court has never held that any other rule applies to claims alleged under the Washington Products Liability Act.
- No court in Connecticut, Indiana, Kansas, New Jersey, Ohio, Tennessee, or Washington has ever held that allegations of latent "subcellular injury" satisfy the elements of a Products Liability Act claim, and accordingly Plaintiffs' allegation of latent "subcellular injury" fails to state a claim.

• Breach of Express and Implied Warranty (Counts X-XII)

- o For Plaintiffs' breach of warranty claims, the District Court asked whether "the elements of those claims are sufficiently pleaded, i.e., whether factual allegations about economic harm or subcellular change are sufficient." Remand Op. at 19.
- O In addition to all the arguments for dismissal of Plaintiffs' warranty claims that Respironics asserted in its original and recently renewed Motions to Dismiss the PIAC and the Second Amended Master Personal Injury Complaint, Plaintiffs' express and implied warranty claims also should be dismissed for the independent reason that Plaintiffs fail to allege manifest physical injuries.

- O Under U.C.C. § 2-715(2), on which state law statutory breach of implied warranty claims are based,³ recovery of consequential damages is permitted only where a plaintiff alleges and proves "injury to person or property." Plaintiffs' implied warranty claims here seek only medical monitoring relief, which is a form of consequential economic damages not arising from a personal injury or injury to property.
- All of Plaintiffs' implied warranty claims, in every state, should therefore be dismissed for failure to state a cause of action (Counts X–XI).
- O Plaintiffs' claims alleging breach of express warranty also fail for the independent reason that Respironics' warranty expressly disclaims liability for consequential economic damages arising from an alleged breach of warranty. Such a consequential damages disclaimer is enforceable under the U.C.C., and all of Plaintiffs' breach of express warranty claims, in every state, should accordingly be dismissed.

As explained in more detail below, and as shown in the roadmap at the conclusion of this supplemental brief, Plaintiffs' inability to allege manifest physical injury, along with other pleading deficiencies, compels dismissal with prejudice of the majority of Plaintiffs' claims under the laws of most states. *See Baker v. Croda Inc.*, No. 21-3360, 2023 WL 5993109, at *1 (3d Cir. Sept. 15, 2023) (affirming dismissal of proposed class action for medical monitoring damages where complaint "failed to allege the existence of a present injury" because "[t]he class cannot show it has suffered any injury under Delaware law.") (citation omitted).

³ "Warranties relevant to products liability cases are generally governed by the provisions of the Uniform Commercial Code and its variations as adopted by the states[.]" 63 Am. Jur. 2d Products Liability § 576.

II. ARGUMENT

A. Negligence and Strict Liability Claims (Counts I-II, V-IX)

The District Court recognized that tort claims traditionally require an "injury" and has requested an assessment of whether Plaintiffs' allegation of "economic harm or subcellular harm will satisfy that element." Remand Op. at 19. For Plaintiffs' negligence and products liability claims (Counts I-II, V-IX), all states traditionally require allegations of a "manifest physical injury" to state a claim for which relief can be granted. While a small minority of states have created an exception to that requirement for medical monitoring claims, most jurisdictions adhere to the traditional rule, and no court, in any state, has ever held that allegations of "economic harm" or latent "subcellular injury" satisfy the requirement to allege a manifest physical injury.

1. The traditional rule in all states requires Plaintiffs to allege a manifest physical injury to state a tort claim, which is not satisfied by allegations of latent "subcellular injury" or economic harm.

Historically, the compensable injury in negligence and products liability actions has been limited to manifest physical injury to person or property.⁴ Tort law traditionally has protected plaintiffs only from the invasion of their interest in avoiding physical harm by unintentional acts and defective products. "The threat of future harm" from exposure to a hazardous substance, by itself, is not an actionable injury sufficient to sustain a cause of action "under generally applicable principles of tort law." *Schweitzer v. Consol. Rail Corp.*, 758 F.2d 936, 942 (3d Cir. 1985)

⁴ E.g., Hinton ex rel. Hinton v. Monsanto Co., 813 So. 2d 827, 829 (Ala. 2001) (holding the present physical injury requirement is a "traditional tort-law requirement" that has existed for hundreds of years); Wood v. Wyeth-Ayerst Lab'ys, Div. of Am. Home Prod., 82 S.W. 3d 849, 851-52 (Ky. 2002); RESTATEMENT (SECOND) OF TORTS § 924, comment a (1979) ("[T]here is no liability for merely negligent conduct that threatens bodily harm[.]"); RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 1 comment d (1998) (limiting recovery for defective products to "harm to persons or property," "commonly referred to as personal injury and property damage"); id. § 6 (limiting recovery for defective medical devices to "harm to persons").

(discussing W. Prosser and P. Keeton, Prosser and Keeton on Torts (5th ed. 1984) at 165); *see also Hinton*, 813 So. 2d at 829 ("[T]hreat of [] harm . . . is not enough"); *Henry v. Dow Chem. Co.*, 701 N.W. 2d 684, 689–90 (Mich. 2005) (same). A manifest physical injury is a practical, functional impairment of bodily functions. *Sondag v. Pneumo Abex Corp.*, 55 N.E. 3d 1259, 1264–65 (Ill. Ct. App. 2016) (rejecting argument that asymptomatic pleural plaques and interstitial fibrosis constitute physical harm absent a showing of resulting loss or detriment to the plaintiff); RESTATEMENT (THIRD) OF TORTS: PHYS. & EMOT. HARM § 4 comment *c* (2010) (defining "physical harm" to require "impairment of the human body," which does not include any need to undergo medical monitoring before such impairment).

Plaintiffs do not allege a manifest physical injury here. Instead, Plaintiffs allege in conclusory fashion that each of them has "suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases." MMSAC at \$\mathbb{Q} 25\$; see also \$\mathbb{Q} \mathbb{Q} 26-88\$ (repeating allegation verbatim for each plaintiff). Plaintiffs do not claim that any "subcellular" changes are causing them present bodily impairment. See id. \$\mathbb{Q} 367\$ (admitting Plaintiffs and putative class members do not have a "recognized" or "manifest" "illness, disease, or disease process"). Plaintiffs, in fact, admit that they allege only "latent" subcellular changes. Id. \$\mathbb{Q} 384\$ (alleging "subcellular or other latent physiological changes"). "Latent" is the opposite of "manifest," and thus latent changes are not actionable injury under traditional tort law. See In re Paoli R.R. Yard PCB Litig., 113 F.3d 444, 458 (3d Cir. 1997) (distinguishing latent from manifest injuries); Schweitzer, 758 F.2d at 942 ("[S]ubclinical injury... is insufficient to constitute the actual loss or damage... required... under generally applicable principles of tort law[.]"); Rainer v. Union Carbide Corp., 402 F.3d 608, 621 (6th Cir. 2005) ("Accepting the plaintiffs' claim would \$\mathbb{Q}\$ [throw open the possibility of litigation by any

person experiencing even the most benign subcellular damage.") (Kentucky law); *Sondag*, 55 N.E. 3d at 1264 (physical harm "means more than an alteration to the structure of one's body.").

The practical problems implicated by a rule permitting claims based solely on alleged latent "subcellular injury" are self-evident. Merely drinking a hot beverage, aging, or even *thinking* cause "physiological changes" at the cellular and subcellular level. That simply is not enough to plausibly allege a right to recover damages. "All life is change, but all change is not injurious." *Dumontier v. Schlumberger Tech. Corp.*, 543 F.3d 567, 570 (9th Cir. 2008).

Accordingly, every court that has considered it has rejected the argument that allegations of latent "subcellular injury" constitute an actionable, manifest physical injury for purposes of stating a claim in tort. See Parker v. Wellman, 230 F. App'x 878, 882 (11th Cir. 2007) (rejecting assertion that subcellular damage is "a current physical injury under Georgia law"); In re Rezulin Prods. Liab. Litig., 361 F. Supp. 2d 268, 273-78 (S.D.N.Y. 2005) (subcellular mitochondrial damage insufficient to establish present physical injury under Louisiana and Texas law); Walston v. Boeing Co., 334 P.3d 519, 522 (Wash. 2014) ("[A]symptomatic cellular-level injury . . . is not itself a compensable injury[.]") (citation omitted); Pounders v. Enserch E & C, Inc., 306 P.3d 9, 14 (Ariz. 2013) (until "the disease is discoverable[,]" "a legally compensable injury does not exist" "based on subcellular injuries occurring at exposure"); Bernier v. Raymark Indus., Inc., 516 A.2d 534, 543 (Me. 1986) ("[M]icroscopic injury . . . is 'insufficient to constitute the actual loss or

⁵ The only state where courts consider allegations of "subcellular injury" for purposes of a medical monitoring claim is Massachusetts. But there, as discussed below, courts do not equate an allegation of *latent* "subcellular injury" with a manifest physical injury. Rather, courts in Massachusetts require medical monitoring plaintiffs to allege and prove "subcellular injury" caused by exposure to a hazardous substance as a precondition to showing a sufficiently heightened risk of contracting a latent disease to be able to state a claim for medical monitoring relief. *Donovan v. Philip Morris USA, Inc.*, 914 N.E. 2d 891, 901 (Mass. 2009).

damage . . . required . . . under generally applicable principles of tort law[.]"") (citation omitted).6

Similarly, allegations of pure economic losses—meaning financial losses not arising from physical injury to person or property—are not an actionable injury for purposes of stating a negligence or products liability claim.⁷ Such purely economic losses are not an actionable "injury" in tort for several reasons, including avoiding indeterminate tort liability and deference to parties' ability to manage economic risk through negotiated contracts (including insurance).⁸ RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR ECONOMIC HARM § 1, comment *c* (2020).

Plaintiffs' allegations of latent "subcellular injury" and pure economic losses accordingly are not actionable "injuries" under traditional tort law. Plaintiffs' tort claims under the laws of any state that adheres to the traditional rule, which requires allegations of manifest physical injury,

⁶ See also Parker, 230 F. App'x at 882 (rejecting assertion that cellular damage constitutes "a current physical injury under Georgia law"); In re Rezulin Prods. Liab. Litig., 361 F. Supp. 2d at 273-78 (allegations of subcellular mitochondrial damage insufficient to establish present physical injury under Louisiana and Texas law); Walston, 334 P.3d at 522 ("[A]symptomatic cellular-level injury... is not itself a compensable injury[.]") (citation omitted); Pounders, 306 P.3d at 14 (until "the disease is discoverable... a legally compensable injury does not exist" "based on subcellular injuries occurring at exposure"); Bernier, 516 A.2d at 543 ("[M]icroscopic injury... is 'insufficient to constitute the actual loss or damage... required... under generally applicable principles of tort law."") (citation omitted).

⁷ RESTATEMENT (THIRD) OF TORTS: LIAB. FOR ECONOMIC HARM § 1, comments *a*–*c* (2020) (explaining rule, "An actor has no general duty to avoid the unintentional infliction of economic loss to another"); RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 21 (1998) (explaining economic losses are only actionable where they are caused by harm to person or property other than the defective product); *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181, 186 (Or. 2008) ("[o]ne ordinarily is not liable for negligently causing a stranger's purely economic loss without injuring his person or property.") (alteration in original; citations omitted); Herbert Bernstein, *Civil Liability for Pure Economic Loss Under American Tort Law*, 46 Am. J. Comp. L. 111 (1998) (discussing history of limitations on recovering economic losses through negligence and product liability claims).

⁸ Where economic losses arise from an injury to the plaintiff's person or property, however, they are recoverable through negligence and products liability claims like other consequential damages. *See* Herbert Bernstein, *Civil Liability for Pure Economic Loss Under American Tort Law*, 46 Am. J. Comp. L. 111, 111, 118 (1998); RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 21 (1998).

must be dismissed for failure to state a claim. Lowe, 183 P.3d at 186; RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM § 4 comment c (2010) (claims for medical monitoring without "impairment of the human body" do not constitute claims for "physical harm").

2. Erie prediction requires dismissal of negligence and strict products liability claims under the laws of the Disputed Jurisdictions.

The parties do not dispute here that the Undisputed Minority Rule jurisdictions (California, the District of Columbia, Florida, Maryland, Missouri, Nevada, Pennsylvania, Utah, Vermont, West Virginia, and Massachusetts) have abandoned the manifest physical injury requirement for claims seeking medical monitoring relief. ECF No. 1352 at 47–48. Nor do the parties dispute that the Undisputed Traditional Rule jurisdictions (North Carolina, New Hampshire, and Delaware) adhere to the traditional rule. ECF No. 2368 at 3, n.5. In the R&R, the Special Master found that the remaining Disputed Jurisdictions would adhere to the traditional pleading requirements, and there is no reason to deviate from that conclusion (with the exception of Tennessee, which also should be found to adhere to the traditional rule for reasons explained below).

Determining whether Plaintiffs have stated tort claims under the laws of the Disputed Jurisdictions requires predicting whether the state's highest court would adhere to the traditional rule under *Erie*. ECF No. 2314 at 1, 7. As the Special Master and the District Court already have recognized, Third Circuit precedents provide substantial instruction for making such predictions. Remand Op. at 13–14; R&R at 6–7. District courts must "opt for the interpretation [of state law] that restricts liability" absent a "clear indication," "clear authority," or an "authoritative signal" that the state supreme court would expand liability. Remand Op. at 14–15; *City of Phila. v. Lead Indus. Ass'n, Inc.*, 994 F.2d 112, 115 (3d Cir. 1993); *Travelers Indem. Co. v. Dammann & Co., Inc.*, 594 F.3d 238, 253 (3d Cir. 2010).

Where a state supreme court has not spoken to an issue, decisions of state intermediate appellate courts are accorded significant weight absent some indication that the highest state court would rule otherwise. *City of Phila.*, 994 F.2d at 123; *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 254 (3d Cir. 2010). However, federal courts may not predict an expansion of liability under state law based upon trial court decisions or other federal courts' *Erie* predictions that "jum[p] ahead of the current state of [the relevant jurisdiction's] law." *City of Phila.*, 994 F.2d at 126, n.12. Nor may they do so based upon "policy arguments" or upon a purported "nationwide consensus" of decisions of other states' courts, particularly where in actuality there is a "split of authority among the highest state courts[.]" *Id.* at 126 n.13, 125–26.

The District Court correctly recognized that the starting point of the analysis here is the traditional rule that manifest physical injury is a prerequisite to common law negligence and product liability claims. Remand Op. at 16. Plaintiffs ask the Court to predict that the Disputed Jurisdictions would abandon this traditional rule. ECF No. 2314 at 2–3. The analysis provided in the Detailed State Law Survey section below shows no "clear authority" or "clear indication" to support such a prediction for any of the relevant states. *Infra* Section III. The Court, therefore, should dismiss Counts I–II and V–IX as asserted under the laws of the Disputed Jurisdictions and the Undisputed Traditional Rule Jurisdictions.

3. The district court's decisions in the *Valsartan* case shed no light on the correct analysis or outcome here.

Plaintiffs have erroneously relied on the district court's decisions in the *Valsartan* case to advocate for a contrary conclusion. ECF No. 2314 (Pls. Objs.) at 10; ECF No. 2314-3 at 4 (citing *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig. ("Valsartan")*, No. 19-2875, 2023 WL 1818922, at *68 (D.N.J. Feb. 8, 2023)); ECF No. 2314-3 at 4 (reproducing the relevant appendix from *Valsartan* at 2023 WL 1818922, at *68). But Plaintiffs' reliance is misplaced. The District

Court observed in the Remand Order that the particular *Valsartan* decision on which Plaintiffs have erroneously relied "involved class certification, not a motion to dismiss[,]" but that the *Valsartan* court had issued "four prior opinions on motion to dismiss[.]" Remand Op. at 16 n. 16. On remand, the District Court directed the parties to "analyze those decisions for the Special Master's review to the extent they would be helpful in determining his recommendation about how this court should predict a state's law on any particular issue." *Id.* The *Valsartan* court's decisions are not helpful in determining the issues presented here by Respironics's motion to dismiss.

The *Valsartan* court's class certification ruling is unhelpful because, there, the district court addressed only whether variations in state law created individual inquiries that preclude the use of class procedures. It concluded that deciding the procedural class certification question did not require it to resolve any questions of state substantive law, including whether any given state adheres to the traditional physical injury requirement. *Valsartan*, 2023 WL 1818922, at *68 (App.); ECF No. 2314-3 at 3. Instead, the *Valsartan* court reasoned that it needed only to determine whether the state law issues were common among state sub-class members and could be resolved on a sub-class-wide basis. *Valsartan*, 2023 WL 1818922, at *33, *36; *see also id.* at *68 (explaining in notes that "class certification is NOT a liability ISSUE") (emphasis in original).

The *Valsartan* court's prior motion to dismiss decisions also are unhelpful, because the district court did not determine in those contexts whether the plaintiffs were required to allege manifest physical injury to state a claim for medical monitoring relief under state law. *See* Appendix A-1 to A-6 (Compilation of *Valsartan* Motion to Dismiss Rulings). The *Valsartan* court issued six separate motion to dismiss rulings resolving different categories of arguments, none of which is pertinent to the necessity of pleading manifest physical injury here:

- MTD Opinion 1 considered arguments that certain claims were preempted by federal law and that the court should abstain in favor of the FDA's primary jurisdiction. (Appx. A-1).
- MTD Opinion 2 considered the argument that plaintiffs lacked Article III standing because they failed to allege an injury in fact. (Appx. A-2). The district court rejected that argument and held that alleging exposure to a toxic substance is sufficient to allege an injury in fact.
- MTD Opinion 3 considered defendants' arguments relating to claims for breach of express warranties, for breach of implied warranties, and for violation of the Magnuson-Moss Warranty Act. The court did not consider whether state law requires plaintiffs to allege manifest physical injury to plead tort claims in that context. (Appx. A-3)
- MTD Opinion 4 considered arguments under Fed. R. Civ. P. 12(b)(6) relating to fraud-based claims, including negligent misrepresentation, and strict liability claims for failure to warn and for design defect. The district court did not consider whether state law requires plaintiffs to allege manifest physical injury. (Appx. A-4).
- MTD Opinion 5 considered arguments relating to subsumption of certain claims by various states' Products Liability Acts, Rule 12(b)(6) pleading deficiencies for common law claims of negligence and negligence *per se*, and certain strict liability claims against certain defendants.
 - o In ruling on the plaintiffs' negligence claim, the *Valsartan* court declined to consider whether the claim should be dismissed under the economic loss doctrine under certain states' laws, and did not consider whether any state requires plaintiffs to allege a manifest physical injury to state a claim. (Appx. A-5 at 31).
 - O In the same opinion, the court considered whether the plaintiffs' stand-alone medical monitoring claims should be dismissed because many jurisdictions do not recognize such a claim. The district court dismissed outright stand-alone medical monitoring

claims alleged under the laws of Alabama, Arkansas, Connecticut, Georgia, Kentucky, Louisiana, Michigan, Mississippi, Nebraska, New Jersey, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and Wisconsin. The court observed that its ruling did not "prejudice plaintiffs' seeking recovery for medical monitoring in concert with any other claim in accordance with the laws of those jurisdictions," but it did not consider whether plaintiffs were required to allege a present physical injury in those jurisdictions in order to state a claim. *Id*.

- The district court declined to dismiss stand-alone medical monitoring claims under the laws of Indiana, Iowa, and New Hampshire because, according to the court, these states "have either not, or inconsistently, ruled on allowing an independent medical monitoring claim." (Appx A-5 at 33).
- The Valsartan court's analysis of the stand-alone medical monitoring cause of action in that case is unhelpful here for multiple reasons.
 - *First,* the district court included little or no substantive analysis explaining its reasoning, and did not conduct an *Erie* analysis to predict state law consistent with Third Circuit precedents.
 - Second, since the Valsartan decision, the highest courts of Delaware and New Hampshire have rejected requests to create independent medical monitoring claims. Baker, 2023 WL 5993109, at *1; Brown v. Saint-Gobain Performance Plastics Corp., 300 A.3d 949, 952–53 (N.H. 2023).
 - Finally, Plaintiffs here assert stand-alone medical monitoring claims under the laws of Colorado, Connecticut, Delaware, the District of Columbia, Florida, Massachusetts, Montana, New Hampshire, Pennsylvania, Utah, and West

Virginia. Because Delaware and New Hampshire are now undisputed, the only remaining disputed jurisdictions in which there is a question whether a standalone medical monitoring claim is cognizable are Colorado, Connecticut, and Montana. Although the *Valsartan* court correctly dismissed the plaintiffs' stand-alone medical monitoring claim under Connecticut law (Appx. A-5 at 17), it did not state whether the plaintiffs asserted a claim under Colorado or Montana law, and did not consider whether Colorado or Montana would permit such a claim. As shown in the Detailed State Survey below, this Court should find that Colorado and Montana do not recognize an independent cause of action for medical monitoring damages.

• MTD Opinion 6 considered defendants' arguments for dismissal of plaintiffs' claims alleging FDA Liaisons, Wrongful Death, Survival Actions, Loss of Consortium, Punitive Damages, and Unjust Enrichment. The court did not consider whether plaintiffs were required to allege a manifest physical injury to state a claim under state law in that context. (Appx. A-6).

B. Fraud and Negligent Misrepresentation Claims (Counts XIII and III)

The District Court dismissed without prejudice Plaintiffs' fraud claim alleged in the PIAC for failure to plead fraud with requisite particularity under Federal Rule of Civil Procedure 9(b). ECF No. 2471 at 7. Plaintiffs' fraud claims in the MMSAC are premised on the same unadorned, conclusory allegations. ECF No. 1351 at 13–14; *compare* MMSAC ¶¶ 677–90 *with* PIAC ¶¶ 563–76. Plaintiffs' fraud claim in the MMSAC (Count XIII) should be dismissed on the same grounds. Respironics likewise incorporated by reference its arguments for dismissal of Plaintiffs'

⁹ While plaintiffs generally do not need to allege manifest physical injury to plead fraud or negligent misrepresentation causes of action, research has uncovered no authority in any jurisdiction expressly recognizing that medical monitoring as an available remedy for such claims.

claim alleging Negligent Misrepresentation presented in its Motion to Dismiss the PIAC. ECF No. 1351 at 13. In the District Court's Order granting in part Respironics' Motion to Dismiss the PIAC, the Court adopted the Special Master's recommendation to dismiss negligent misrepresentation claims under Alabama, Arkansas, Connecticut, Idaho, Indiana, Maine, New York, North Carolina, South Dakota, and Virginia law. *See* ECF No. 2471 at 18; *see also* ECF No. 2271 at 58-75. The District Court also granted with prejudice Respironics' motion to dismiss the PIAC's negligent misrepresentation claims under Minnesota law. ECF No. 2471 at 18. Plaintiffs' duplicate claim in the MMSAC should be dismissed to the same extent.

C. Independent Medical Monitoring Claim (Count IV)

A small minority of states have created an exception to the manifest physical injury requirement by recognizing a new, independent medical monitoring cause of action. Plaintiffs assert such a claim under the laws of eleven states. MMSAC ¶¶ 481-99. Respironics agrees that, as a general matter, a stand-alone medical monitoring claim is cognizable under the laws of the District of Columbia, Florida, Massachusetts, Pennsylvania, Utah, and West Virginia. However, no such claim exists in Delaware, New Hampshire, Colorado, Connecticut, and Montana.

Plaintiffs have abandoned their Delaware and New Hampshire claims following recent decisions of those states' highest courts declining to adopt an independent medical monitoring cause of action. ECF No. 2368 at 1 n.2.

As shown in the State Law Survey below, the three remaining states (Colorado, Connecticut, and Montana) have not recognized an independent medical monitoring cause of action, and their highest courts have given no indication that they would do so. *Infra* Sections III.C.3, III.C.4 and III.C.14. In the absence of such a clear indication, this "Court cannot invent new state law claims." *Banks v. E.I. du Pont de Nemours and Co.*, No. 19-1672, 2022 WL 3139087, at *9 (D. Del. Aug. 4, 2022). Plaintiffs' independent medical monitoring claims brought

under the laws of Colorado, Connecticut, and Montana should therefore be dismissed.

D. Products Liability Act Claims (Count XIV)

Plaintiffs' Products Liability Act claims (Count XIV) also should be dismissed for similar reasons. These claims are premised on the Products Liability Acts of New Jersey, Connecticut, Indiana, Kansas, Ohio, Tennessee, and Washington. Each of these statutes requires allegations of a manifest physical injury to state a claim for which relief can be granted.

1. New Jersey.

The New Jersey Products Liability Act ("NJPLA") defines a "product liability action" as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." *Sinclair*, 948 A.2d at 593 (quoting N.J.S.A. 2A:58C–1(b)(3)). The NJPLA further defines "harm" as (a) physical damage to property, other than to the product itself; (b) *personal physical illness, injury, or death*; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph." *Id*. (emphasis in original).

The New Jersey Supreme Court interpreted the NJPLA "to require a physical injury." Sinclair, 948 A.2d at 595. The court grounded this holding in a textual interpretation of the NJPLA, and in its pre-NJPLA adoption of the view of Restatement (Second) of Torts § 402A (1965), in which strict liability in tort for defective products spoke only in terms of physical harm. Id. It also found that the legislative history of the NJPLA did not evince an intent to "eliminate that physical component." Id. Accordingly, New Jersey requires plaintiffs asserting any claim for

¹⁰ The products liability acts of Connecticut, Indiana, Kansas, Ohio, and Tennessee (among others) similarly define "harm" or "injury" (*Id.* at 594, n.1), and the Washington Supreme Court has interpreted its act to require physical injury (*Id.* at 595 n.2 (citing *Lenhardt v. Ford Motor Co.*, 683 P.2d 1097, 1099 (Wash. 1984) (en banc)).

harm from a product to plead and prove a present physical injury, a requirement which cannot be avoided by bringing the claim under a different name (*e.g.*, a negligence or consumer protection claim). *Id.* at 595–96; *id.* at 589 ("[T]he [NJPLA] is the sole source of remedy for plaintiff's defective product claim[.]").

In *Sinclair*, the plaintiffs filed a class action complaint against the manufacturers, advertisers, sellers, marketing partners, and promoters of the drug Vioxx alleging claims for negligence, violations of the NJPLA and New Jersey's Consumer Fraud Act, breach of express and implied warranties, and unjust enrichment. 948 A.2d at 589. The plaintiffs alleged that by ingesting Vioxx they "are at enhanced risk of serious undiagnosed and unrecognized myocardial infarction, commonly referred to as 'silent heart attack,' and other latent and unrecognized injuries." *Id.* They sought medical monitoring costs, claiming that such costs represent "an ascertainable economic loss." *Id.*

The New Jersey Supreme Court determined that "the heart of plaintiffs' case is the potential for harm caused by Merck's drug"—"[i]t is obviously a product liability claim." *Sinclair*, 948 A.2d at 596. Because the *Sinclair* plaintiffs did not allege "manifest injury[,]" *id.* at 589, the court held that they failed to state a claim and, because the NJPLA was their exclusive remedy, it barred the plaintiffs' remaining claims. *Id.* at 595–96.

So too here. Plaintiffs' claims all allege "the potential for harm caused by [a product]," and thus fall within the scope of the NJPLA—with the lone exception of the breach of express warranty claim (Count XII). *Sinclair* expressly rejected Plaintiffs' argument that the NJPLA's manifest physical harm requirement can be met by economic loss from the cost of future medical monitoring procedures or by allegations of "enhanced risk" of "latent and unrecognized injuries." *Sinclair*, 948 A.2d at 589, 594–95. And *Sinclair's* reasoning precludes any contention that

"subcellular or other latent physiological changes" constitute manifest physical injury.

2. Connecticut.

Under the Connecticut Products Liability Act ("CPLA"), "[a] product liability claim . . . may be asserted and shall be in lieu of all other claims against product sellers, including actions of negligence, strict liability and warranty, for harm caused by a product." *Gerrity v. R.J. Reynolds Tobacco Co.*, 818 A.2d 769, 773 (Conn. 2003) (quoting General Statutes § 52-572n (a)) (emphasis and quotations omitted). "[H]arm" is "damage to property, including the product itself, and personal injuries including wrongful death." General Statutes § 52-572m (d).

The Connecticut Supreme Court has interpreted the CPLA to require allegations of manifest physical personal injuries or property damage, and has held that a "financial injury" alone does not meet this requirement. *Gerrity*, 818 A.2d at 775. Plaintiffs' CPLA claim (Count XIV), therefore, should be dismissed. Economic losses, such as medical monitoring damages not arising from a manifest physical injury, are not actionable "harm" under *Gerrity*.

3. Indiana.

The Indiana Products Liability Act ("IPLA") "governs all actions . . . for physical harm caused by a product . . . regardless of the substantive legal theory or theories upon which the action is brought." Ind. Code Ann. § 34-20-1-1. As in New Jersey, "'[p]hysical harm' is defined as 'bodily injury, death, loss of services, and rights arising from any such injuries, as well as sudden, major damage to property." *DeVane v. Arch Wood Prot., Inc.*, 197 N.E. 3d 343, 346–47 (Ind. Ct. App. 2022) (quoting Ind. Code Ann. § 34-6-2-105(a)).

In *Devane*, the Indiana Court of Appeals held that neither economic harm nor an increased risk of future illness or injury constitute an actionable "physical harm" under the IPLA. 197 N.E. 3d at 347. And in *AlliedSignal*, *Inc.* v. *Ott*, the Indiana Supreme Court held that an IPLA actionable injury "does not occur upon mere exposure" or subclinical physiological change and overruled a

prior decision to the extent it "holds to the contrary[.]" 785 N.E. 2d 1068, 1075, n.8 (Ind. 2003). Rather, the court held that in the case of a latent disease—there, asbestos-related illness—actionable injury does not accrue until the disease is diagnosable. *Id.* at 1075. An IPLA claim does not accrue until the latent injury (*i.e.*, disease) "has actually manifested itself[.]" *Id.*

Accordingly, Plaintiffs fail to plead "physical harm" for purposes of the IPLA, and the Plaintiffs' IPLA claim should be dismissed (Count XIV).

4. Kansas.

The Kansas Products Liability Act ("KPLA") governs "any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product." Kan. Stat. Ann. § 60-3302(c). It defines an actionable "harm" as "(1) Damage to property; (2) personal physical injuries, illness and death; (3) mental anguish or emotional harm attendant to such personal physical injuries, illness or death"—"not direct or consequential economic loss." Kan. Stat. Ann. § 60-3302(d).

Plaintiffs' alleged enhanced risk of future disease fails to state a KPLA claim. In *Harding* v. K.C. Wall Prod., Inc., the Kansas Supreme Court held that a product liability cause of action asserting "latent disease" does not exist until the disease is "diagnosed." 831 P.2d 958, 965 (Kan. 1992). Plaintiffs' asserted economic losses for future medical monitoring are also outside the KPLA's definition of "harm" as "consequential" damages. Kan. Stat. Ann. § 60-3302(d). Plaintiffs' KPLA claim (Count XIV) should be dismissed.

5. Ohio.

Plaintiffs' product liability claim under the Ohio Products Liability Act ("OPLA") fails for the same reasons. Ohio Rev. Code § 2307.71 *et seq.* (Count XIV). The OPLA defines "product liability claim" as "a claim or cause of action . . . that seeks to recover compensatory damages

from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question. . . ." Ohio Rev. Code § 2307.71(A)(13).

Plaintiffs' OPLA claim fails. While "a cause of action may concern a product, it is not a product liability claim within the purview of Ohio's product liability statutes unless it alleges damages other than economic ones[.]" *LaPuma v. Collinwood Concrete*, 661 N.E. 2d 714, 716 (Ohio 1996). "Economic loss" is defined as "direct, incidental, or consequential pecuniary loss, including, but not limited to, damage to the product in question, and nonphysical damage to property other than that product." *Id.* at 716 (quoting Ohio Rev. Code § 2307.71(A)(2)). Here, Plaintiffs' only damages are purely economic: alleged medical monitoring costs. Under Ohio law, any claim for "bodily injury . . . caused by exposure to hazardous or toxic chemicals" does not exist until the injury related to that exposure is diagnosable. Ohio Rev. Code Ann. § 2305.10(B)(1). Plaintiffs' OPLA claim (Count XIV) should be dismissed.

6. Tennessee.

The Tennessee Products Liability Act ("TPLA") defines a "product liability action" as "all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product." Tenn. Code Ann. § 29-28-102(6). It "includes, but is not limited to, all actions based upon the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever[.]" *Id*.

"[W]ithout a claim for personal injury or property damage, no claim may lie under the [TPLA]." *City of Franklin v. W.L. Hailey & Co.*, 634 S.W. 3d 16, 27 (Tenn. Ct. App. 2019). In *Potts v. Celotex Corp.*, the Tennessee Supreme Court held that the risk of contracting a latent disease (there, mesothelioma) from harmful exposure is not a "personal injury" and thus does not accrue until it manifests (*i.e.*, is diagnosable). 796 S.W. 2d 678, 680–81, 684 (Tenn. 1990). Plaintiffs' comparable assertions of an enhanced risk of latent disease, therefore, fail to allege an actionable "personal injury." *Id.* at 681 (explaining that plaintiffs cannot recover damages for an "increased risk of cancer"). Plaintiffs' TPLA claim (Count XIV), therefore, should be dismissed.

7. Washington.

The Washington Products Liability Act ("WPLA") defines "product liability claim" as "any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product." Wash. Rev. Code Ann. § 7.72.010(4). "Although much of the WPLA was taken from the Model Uniform Product Liability Act (UPLA), 44 Fed. Reg. 62, 713 (1979), the legislature chose not to use the UPLA's definition of 'harm'" that has been adopted by other states. *Bylsma v. Burger King Corp.*, 293 P.3d 1168, 1170 (Wash. 2013). The WPLA, instead, defines "harm" to include "any damages recognized by the courts of this state . . . [except for] direct or consequential economic loss under Title 62A RCW." Wash. Rev. Code Ann. § 7.72.010(6) (emphasis added). Under this definition, courts should "look to Washington case law to determine whether the damages in question are 'recognized by the courts of this state." *Bylsma*, 293 P.3d at 1170 (quoting RCW 7.72.010(6)).

Medical monitoring in Washington is a remedy that can be recovered only if the traditional elements of liability are proven, including manifest physical injury. *See Koker v. Armstrong Cork, Inc.*, 804 P.2d 659, 664, 669 (Wash. Ct. App. 1991) (WPLA requires the plaintiff to suffer

"physical harm," and claims seeking "damages for a future harm" from a latent disease are not actionable until "injury results"); *Duncan v. Nw. Airlines, Inc.*, 203 F.R.D. 601, 605–09 (W.D. Wash. 2001) (predicting that Washington courts would not recognize a cause of action for medical monitoring because Washington law requires existing injury in order to pursue a negligence claim); *In re Berg Litig.*, 293 F.3d 1127, 1133 (9th Cir. 2002) (citing *Duncan* with approval); *Hofstee v. Dow*, 36 P.3d 1073, 1076 (Wash. Ct. App. 2001) ("The WPLA explicitly confines recovery to physical harm suffered by persons and property[.]") (citation omitted). Plaintiffs accordingly must allege a manifest physical injury to state a claim for medical monitoring costs under the WPLA.

Because the law of all of the seven states under which Plaintiffs allege Products Liability

Act claims is in accord, and each requires Plaintiffs to allege a manifest physical injury to state a

Product Liability Act claim for medical monitoring damages, Count XIV should be dismissed.

E. Breach of Implied and Express Warranty Claims (Counts X-XII)

The District Court asked the Special Master to consider, with respect to Plaintiffs' breach of warranty claims (Counts X-XII), whether "the elements of those claims are sufficiently pleaded, *i.e.*, whether factual allegations about economic harm or subcellular change are sufficient." Remand Op. at 19. They are not.

Plaintiffs' breach of warranty claims seek consequential damages in the form of "the present and ongoing need to incur the cost of medically necessary diagnostic testing[.]" MMSAC ¶¶ 620, 648. Consequential damages, however, may be recovered only where a breach of warranty

has resulted in "injury to person or property." Ford v. Aldi, Inc., 832 S.W. 2d 1, 2 (Mo. Ct. App. 1992). For all of the reasons stated above, Plaintiffs allege no "injury to person or property" here. Plaintiffs allege only an increased risk of developing an "injury to person" in the future. Plaintiffs' claim for future medical monitoring costs thus fails to state a claim for a recoverable "consequential damage" under the UCC, as adopted by state law. Accordingly, Plaintiffs' implied and express warranty claims must be dismissed. See Ford, 832 S.W. 2d at 2 (holding that plaintiff could not recover consequential emotional distress damages through an implied warranty claim "absent any physical injury," because Section 2-715 requires "injury to person").

Plaintiffs' breach of express warranty claim also fails for the additional reason that the recalled devices' warranty expressly "disclaims all liability for economic loss . . . or consequential damages which may be claimed to arise from any sale or use of this product." ECF No. 916 at 18 (quoting Economic Loss TAC Ex. 47 at 32). ¹² Because such express disclaimers of consequential

^{1 &}quot;Congaguantial damages

^{11 &}quot;Consequential damages resulting from the seller's breach include . . . (b) injury to person or property proximately resulting from any breach of warranty." Unif. Commercial Code § 2-715; Ala. Code § 7-2-715; Alaska Stat. § 45.02.715; Ariz. Rev. Stat. Ann. § 47-2715; Ark. Code Ann. § 4-2-715; Cal. Com. Code § 2715; Colo. Rev. Stat. § 4-2-715; Conn. Gen. Stat. Ann. § 42a-2-715; Del. Code Ann. tit. 6, § 2-715, et seq.; D.C. Code Ann. § 28:2-715; Fla. Stat. Ann. § 672.715, et seg.; O.C.G.A. § 11-2-715, et seg.; Haw. Rev. Stat. § 490:2-715; Idaho Code § 28-2-715; Ill. Comp. Stat. Ann. Ch. 810, 5/2-715; Ind. Code Ann. § 26-1-2-715; Iowa Code Ann. § 554.2715; Kan. Stat. Ann. § 84-2-715; Me. Rev. Stat. Ann. tit. 11, § 2-715; Md. Code Ann., Com. Law § 2-715; Mass. Gen. Laws Ann. Ch. 106, § 2-715; Minn. Stat. Ann. § 336.2-715; Mo. Rev. Stat. § 400.2-715; Mont. Code Ann. § 30-2-715; Neb. Rev. Stat. § 2-715; Nev. Rev. Stat. § 104.2715; N.H. Rev. Stat. Ann. § 382-A:2-715; N.J. Stat. Ann. § 12A:2-715; N.M. Stat. Ann. § 55-2-715; N.Y. U.C.C. Law § 2-715; N.C. Gen. Stat. Ann. § 25-2-715; Ohio Rev. Code Ann. § 1302.89; Okla. Stat. tit. 12A, § 2-715; Or. Rev. Stat. § 72.7150; 13 Pa. Stat. Ann. § 2715; R.I. Gen. Laws § 6A-2-715; S.C. Code Ann. § 36-2-715; Tenn. Code Ann. § 47-2-715; Tex. Bus. & Com. Code § 2.715; Utah Code Ann. § 70A-2-715; Va. Code Ann. § 8.2-715; Vt. Stat. Ann. tit. 9A, § 2-715; Wash. Rev. Code § 62A.2-715; and W. Va. Code § 46-2-715.

¹² Respironics argued in its motion to dismiss the Economic Loss Master Complaint that the Recalled Devices' express warranty disclaims consequential damages claims for economic losses.

damages are enforceable under the Uniform Commercial Code, Plaintiffs' claims for consequential economic damages in the form of medical monitoring costs resulting from an alleged breach of express warranty, and not arising from a personal injury, should be dismissed for this reason as well. *See* U.C.C. §§ 2-7219(1)(a), 2-719(3)).

Under the plain text of U.C.C. section 2-715(2), as incorporated by state statutes, consequential economic damages may be recovered only where a breach of warranty has resulted in "injury to person or property." See Ford, 832 S.W. 2d at 2.

III. DETAILED STATE LAW SURVEY

This section analyzes the law of each relevant state, as requested by the District Court, and demonstrates that the majority of state high courts that have addressed the issue have adhered to the traditional manifest physical injury pleading requirement for medical monitoring claims and for claims asserted under Product Liability Acts in certain relevant jurisdictions. They have generally echoed the concerns expressed by the United States Supreme Court in *Metro-North Commuter Railroad Company v. Buckley*, 521 U.S. 424 (1997) that altering the traditional rule brings with it a risk of (i) overloading the courts with endless litigation brought by millions of plaintiffs who allege that they were exposed to hazardous substances but are not sick, ¹⁴ (ii) diminishing the resources available to compensate plaintiffs suffering actual physical injuries, ¹⁵

See ECF 916 at 18. Respironics's Motion to Dismiss the Economic Loss Master Complaint was rendered moot by the parties' settlement, but Respironics incorporated the same argument into its Motion to Dismiss the MMSAC, as it applies in full to Plaintiffs' breach of express and implied warranty claims here (Count X–XII).

[&]quot;Consequential damages resulting from the seller's breach include ... (b) injury to person or property proximately resulting from any breach of warranty." Unif. Commercial Code § 2-715.

¹⁴ Baker, 304 A.2d at 196; Berry, 181 N.E. 3d at 688; Henry, 701 N.W. 2d at 694–95; Wood, 82 S.W. 3d at 857–58; Hinton, 813 So. 2d at 831.

¹⁵ Baker, 304 A.2d at 196–97; Henry, 701 N.W. 2d at 690–91, 696; Wood, 82 S.W. 3d at 857; Hinton, 813 So. 2d at 831.

and (iii) creating uncertainty both in predicting and in determining liability.¹⁶ In light of these policy considerations, the highest courts of most jurisdictions have since *Buckley* generally held that the decision to abandon the traditional rule is best left to the legislature.¹⁷

The minority of states that have diverged from the traditional rule did so based on a policy driven determination to treat the freedom from the economic costs associated with future medical monitoring as a legally protected interest. Under Third Circuit precedent, this Court should predict that the Disputed Jurisdictions will decline to recognize such freedom as a distinct protected interest, and instead will continue to adhere to the manifest physical injury requirement, as demonstrated below.

A. Undisputed Traditional Rule Jurisdictions that Adhere to the Manifest Physical Injury Pleading Requirement.

1. North Carolina.

In *Curl v. American Multimedia, Inc.*, 654 S.E. 2d 76, 81 (N.C. Ct. App. 2007), the court held that medical monitoring costs are merely another form of relief, available if the plaintiff proves the required elements for liability, including "present injury." 654 S.E. 2d at 81. The *Curl* plaintiffs, however, alleged no manifest physical injury. Instead, they argued that "traditional tort law" permits claims based on "(1) infliction of a loss of chance of continued health/increased risk

¹⁶ Berry, 181 N.E. 3d at 688; Henry, 701 N.W. 2d 690–91; Hinton, 813 So. 2d at 831.

 $^{^{17}}$ Baker, 304 A.2d at 197; Brown, 300 A.3d at 952; Henry, 701 N.W. 2d at 695, 697; Wood, 82 S.W. 3d at 858.

¹⁸ Friends for all Children, 746 F.2d at 826; Ayers, 525 A.2d at 304, 310–12; Hansen, 858 P.2d at 976–78; Simmons, 674 A.2d at 235–240, n.11; Petito, 750 So. 2d at 104–06; Bower, 522 S.E. 2d at 428–31; Meyer ex rel. Coplin v. Fluor Corp., 220 S.W. 3d 712, 716-18 (Mo. 2007); Exxon Mobil, 71 A.3d at 75–76, 80; Sadler, 340 P.3d at 1270–71; see also Potter, 863 P.2d at 822–23 (taking a slightly different approach, broadly interpreting California's Civil Code to allow claims based on economic costs of medical monitoring and supporting this determination with policy analysis).

of serious disease; (2) an invasion of personal autonomy, specifically of the right not to be compelled to undergo heightened medical monitoring for the remainder of their lives; and (3) the instilling of fear of cancer or other deadly disease." *Id.* at 80–81. The appellate court rejected these arguments and held that North Carolina requires a manifest physical injury to state a claim in tort for medical monitoring damages, recognizing that "the increased risk of disease as a present injury, or of the cost of medical monitoring as an element of damages, will present complex policy questions ... within the purview of the legislature and not the courts." *Id.* at 81.

The federal district court in *Priselac v. Chemours Co.* correctly held that *Curl* dictated an *Erie* prediction that the highest court of North Carolina would not abandon the traditional manifest physical injury requirement for claims seeking medical monitoring damages. No. 7:20-cv-190, 2022 WL 909406, at *3 (E.D.N.C. Mar. 28, 2022) ("Under North Carolina law, medical monitoring is not cognizable as an independent cause of action or an element of damages absent a present physical injury.").

2. New Hampshire.

In *Brown v. Saint-Gobain Performance Plastics Corp.*, 300 A.3d 949 (N.H. 2023), the Supreme Court of New Hampshire held that "the mere existence of an increased risk of future development of disease is not sufficient under New Hampshire law to constitute a legal injury for purposes of stating a claim for the costs of medical monitoring as a remedy or as a cause of action in the context of plaintiffs who were exposed to a toxic substance but have no present physical injury." *Id.* at 952. The court rejected the argument that an alleged need to incur medical monitoring costs in the future is an actionable injury. *Id.* "[T]he plaintiffs' characterization of their 'injury' as 'the present need for and cost of diagnostic testing' conflates 'an allegation of 'injury,' which is 'an instance of actionable harm,' with 'a claim for 'damages,' that is, 'a sum of money awarded to one who has suffered an injury." *Id.* In making this conflation, "the plaintiffs

effectively conceded that they do not, at present have an injury." Id. (emphasis in original).

3. Delaware.

In *Baker v. Croda Inc.*, 304 A.3d 191 (Del. 2023) the court recognized that "Delaware tort law presupposes that plaintiffs will bring suits after they suffer physical symptoms, not before," noting that "the statute of limitations for toxic tort claims starts to run when a plaintiff begins to experience *physical effects.*" *Id.* at 196 (emphasis in original). Accordingly, the court declined to abandon the present physical injury requirement for medical monitoring claims, holding that "an increased risk of harm only constitutes a cognizable injury when manifested by physical illness." *Id.* at 197. Plaintiffs' allegations of "subcellular or other latent physiological changes" that increase the risk of future disease is not "cognizable injury" in Delaware.

B. Undisputed Minority Rule Jurisdictions that Permit Claims for Medical Monitoring Relief Without Allegation of Manifest Physical Injury (and Elements Where Specified).

1. District of Columbia.

In *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, the United States Circuit Court for the District of Columbia predicted that the District of Columbia would permit a plaintiff to "maintain an action for diagnostic examinations in the absence of proof that he or she was physically injured." 746 F.2d 816, 824–26 (D.C. Cir. 1984). ¹⁹ The District of Columbia courts have not articulated the elements that a plaintiff must plead to state a claim for medical monitoring.

2. New Jersey.

In Ayers v. Jackson Township, the Supreme Court of New Jersey held "that the cost of medical surveillance is a compensable item of damages where the proofs demonstrate, through

¹⁹ The Undisputed Minority Rule jurisdictions in this section are listed in the chronological order in which each was held to have abandoned the manifest physical injury requirement for purposes of alleging a claim for medical monitoring relief.

reliable expert testimony predicated upon the significance and extent of exposure to chemicals, the toxicity of the chemicals, the seriousness of the diseases for which individuals are at risk, the relative increase in the chance of onset of disease in those exposed, and the value of early diagnosis, that such surveillance to monitor the effect of exposure to toxic chemicals is reasonable and necessary." 525 A.2d 287, 312 (N.J. 1987).

However, the fact that the New Jersey Supreme Court permitted no-injury medical monitoring claims in *Ayers* is of no help to Plaintiffs here, because Plaintiffs' claims are products liability claims that are subsumed by the NJPLA. In *Sinclair*, the New Jersey Supreme Court held that the NJPLA requires manifest physical injury for any claim asserting "potential harm" "caused by a product," *supra* Section II.D.1; *Sinclair*, 948 A.2d at 595, and that the NJPLA subsumes all products liability causes of action, including Plaintiffs' claims here. *Id.* Accordingly, Plaintiffs' negligence and products liability claims under New Jersey law should be dismissed notwithstanding *Ayers*.

3. California.

In *Potter v. Firestone Tire & Rubber Co.*, the Supreme Court of California held that medical monitoring costs could be recovered in a negligence action without proof of present physical injury or "future injury that is more likely than not to occur" provided the plaintiff can plead and prove facts establishing that "the need for future monitoring is a reasonably certain consequence of a plaintiff's toxic exposure and that the recommended monitoring is reasonable." 863 P.2d 795, 822–25 (Cal. 1993).

"In determining the reasonableness and necessity of monitoring, the following factors are relevant: (1) the significance and extent of the plaintiff's exposure to chemicals; (2) the toxicity of the chemicals; (3) the relative increase in the chance of onset of disease in the exposed plaintiff as a result of the exposure, when compared to (a) the plaintiff's chances of developing the disease

had he or she not been exposed, and (b) the chances of the members of the public at large of developing the disease; (4) the seriousness of the disease for which the plaintiff is at risk; and (5) the clinical value of early detection and diagnosis." *Id.* at 824–25.

4. Utah.

In *Hansen v. Mountain Fuel Supply Co.*, the Supreme Court of Utah held that a plaintiff could state a claim to recover medical monitoring damages without alleging a present physical injury if the plaintiff alleges and proves "the following: (1) exposure (2) to a toxic substance, (3) which exposure was caused by the defendant's negligence, (4) resulting in an increased risk (5) of a serious disease, illness, or injury (6) for which a medical test for early detection exists (7) and for which early detection is beneficial, meaning that a treatment exists that can alter the course of the illness, (8) and which test has been prescribed by a qualified physician according to contemporary scientific principles." 858 P.2d 970, 975–81 (Utah 1993).

5. Pennsylvania.

In Simmons v. Pacor, Inc., the Supreme Court of Pennsylvania held that a claim for medical monitoring costs can be stated without alleging a manifest physical injury. 674 A.2d 232, 239 (Pa. 1996). The following year, in Redland Soccer Club, Inc. v. Department of the Army & Department of Defense of the U.S., 696 A.2d 137, 145–46 (Pa. 1997), the court established the elements for a medical monitoring claim: "(1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles."

6. Florida.

In *Petito v. A.H. Robins Co.*, 750 So. 2d 103, 105–08 (Fla. Dist. Ct. App. 1999), the court held that "a trial court may use its equitable powers to create and supervise a fund for medical monitoring purposes"—even if the plaintiff does not have a present physical injury—if she proves: "(1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and, (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles."

7. West Virginia.

In West Virginia a plaintiff may state a medical monitoring claim upon allegations: "that (1) he or she has, relative to the general population, been significantly exposed; (2) to a proven hazardous substance; (3) through the tortious conduct of the defendant; (4) as a proximate result of the exposure, plaintiff has suffered an increased risk of contracting a serious latent disease; (5) the increased risk of disease makes it reasonably necessary for the plaintiff to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of the exposure; and (6) monitoring procedures exist that make the early detection of a disease possible." *Bower v. Westinghouse Elec. Corp.*, 522 S.E. 2d 424, 432–33 (W. Va. 1999).

8. Missouri.

Under Missouri law "a plaintiff can obtain damages for medical monitoring" without alleging present physical injury, "upon a showing that 'the plaintiff has a significantly increased risk of contracting a particular disease relative to what would be the case in the absence of exposure" and "that 'medical monitoring is, to a reasonable degree of medical certainty necessary

in order to diagnose properly the warning signs of disease." Meyer, 220 S.W. 3d at 718.

9. Massachusetts.

To state a claim for medical monitoring damages without alleging a manifest physical injury, a plaintiff must allege that: "(1) The defendant's negligence (2) caused (3) the plaintiff to become exposed to a hazardous substance that produced, at least, subcellular changes that substantially increased the risk of serious disease, illness, or injury (4) for which an effective medical test for reliable early detection exists, (5) and early detection, combined with prompt and effective treatment, will significantly decrease the risk of death or the severity of the disease, illness or injury, and (6) such diagnostic medical examinations are reasonably (and periodically) necessary, conformably with the standard of care, and (7) the present value of the reasonable cost of such tests and care, as of the date of the filing of the complaint." *Donovan v. Philip Morris USA, Inc.*, 914 N.E. 2d 891, 902 (Mass. 2009).

10. Maryland.

In Exxon Mobil Corp. v. Albright, the Maryland Court of Appeals held that medical monitoring costs are recoverable as a remedy without proof of physical injury, provided that the plaintiff proves that they are "reasonable" and "necessary due to a reasonably certain and significant increased risk of developing a latent disease as a result of exposure to a toxic substance." 71 A.3d 30, 81–82 (Md. 2013). "In awarding relief, a court must consider whether the plaintiff has shown: (1) that the plaintiff was significantly exposed to a proven hazardous substance through the defendant's tortious conduct; (2) that, as a proximate result of significant exposure, the plaintiff suffers a significantly increased risk of contracting a latent disease; (3) that increased risk makes periodic diagnostic medical examinations reasonably necessary; and (4) that monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial." *Id.* at 81–82.

"To determine what is a 'significantly increased risk of contracting a latent disease' for a particular plaintiff, the court may consider quantifiable and reliable medical expert testimony that indicates the plaintiff's chances of developing the disease had he or she not been exposed, compared to the chances of the members of the public at large of developing the disease." *Id.* at 82. If the "plaintiff sustains his or her burden of proof in recovering this form of relief, the court should award medical monitoring costs ordinarily by establishing equitably a fund, administered by a trustee, at the expense of the defendant." *Id.* at 82.

11. Nevada.

In Sadler v. PacifiCare of Nev., the Supreme Court of Nevada held that "a plaintiff may state a cause of action for negligence with medical monitoring as the remedy without asserting that he or she has suffered a present physical injury." 340 P.3d 1264, 1270 (Nev. 2014). "[I]n a negligence action for which medical monitoring is sought as a remedy, a plaintiff may satisfy the injury requirement for the purpose of stating a claim by alleging that he or she is reasonably required to undergo medical monitoring beyond what would have been recommended had the plaintiff not been exposed to the negligent act of the defendant." *Id.* at 1272.

12. Vermont.

The Vermont General Assembly has created a statutory medical monitoring cause of action. See Vt. Stat. Ann. tit. 12, §§ 7201, 7202. Under the statute, a person "without present injury or disease" may assert a cause of action for medical monitoring costs upon proof of: "(1) exposure at a rate significantly greater than the general population; (2) to a proven toxic substance; (3) as a result of tortious conduct of the defendant; (4) as a proximate result of the exposure, plaintiffs have suffered an increased risk of contracting a serious disease; (5) the increased risk makes it medically necessary for the plaintiffs to undergo periodic medical examination different from that prescribed for the general population in the absence of exposure;

and (6) monitoring procedures exist that are reasonable in cost and safe for use." *Id.*

C. Disputed Jurisdictions for Which the Court Should Predict that the State's Highest Court Would Adhere to the Manifest Physical Injury Requirement for Tort Claims Seeking Medical Monitoring Relief.

1. Arizona.

The Arizona Supreme Court held in *Quiroz v. ALCOA Inc.*, 416 P.3d 824 (Ariz. 2018), that plaintiffs alleging nuisance and products liability claims must allege a manifest physical injury in order to state a claim. Plaintiffs asserting a nuisance claim, however, can seek medical monitoring relief without alleging a manifest physical injury. *Id.* Plaintiffs here do not allege a nuisance claim, and their negligence and products liability claims fail to state a cause of action.

In *Burns v. Jaquays Min. Corp.*, 752 P.2d 28, 30 (Ariz. Ct. App. 1987), plaintiffs sought medical monitoring damages without alleging a manifest physical injury and asserted causes of action for negligence, strict liability, and nuisance. 752 P.2d at 30. Addressing the negligence and strict liability claims, the *Burns* court refused "to depart from traditional tort concepts and allow recovery for injuries before any disease becomes manifest," noting that "[t]he statute of limitations does not begin to run until there is a manifestation of physical injuries or disease." *Id.* at 31; *see also Pounders v. Enserch E & C, Inc.*, 306 P.3d 9, 13 (Ariz. 2013) (holding that "[f]or long-latency diseases . . . a legally compensable injury does not exist" until "the disease is discoverable"—*i.e.*, "upon manifestation," not subclinical change). On the other hand, the intermediate appellate court held that nuisance claims for medical monitoring damages do not require plaintiffs to allege a manifest physical injury to state a claim. *Id.* at 32.

Thirty years later, the Arizona Supreme Court considered *Burns* and refined its holding. There, the Court explained that *Burns* "held that the residents had no cognizable negligence claim because the risk of future injuries was insufficient to prove the requisite element of 'actual loss or damage[s]" and that "the medical costs associated with monitoring the residents' subclinical

injuries was recoverable in the context of a nuisance claim." *Quiroz*, 416 P.3d at 832-33 (citing *Burns*, 752 P.2d at 29, 32–34). The original R&R, therefore, correctly recognized that *Burns*—an intermediate appellate court opinion—did not provide a basis to predict that Arizona would abandon the present physical injury requirement, particularly after the Arizona Supreme Court's clarification of *Burns* in *Quiroz*. ECF No. 2273 (R&R) at 8 n.4.

Plaintiffs have erroneously relied on *Valsartan* to advocate for the contrary conclusion, but their reliance is misplaced. *See* Remand Op. at 16, n. 16; ECF No. 2314 (Pls. Objs.) at 10; ECF No. 2314-3 at 4 (citing *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, No. 19-2875, 2023 WL 1818922 *68 (D.N.J. Feb. 8, 2023)); ECF No. 2314-3 at 4 (reproducing the relevant appendix from *Valsartan* at *68). *Valsartan* 's analysis of Arizona law is limited to a lengthy quote from *Burns* that ignores both context and the Arizona Supreme Court's subsequent clarification in *Quiroz*, as explained above. ECF No. 2314-3 at 4.

Plaintiffs also argue that Arizona would recognize a tort claim seeking medical monitoring costs "without proof of present physical injury" because it either has adopted or would adopt "the definition of injury and harm in [Restatement (Second) of Torts § 7 (1965)] and determine that economic loss caused by the medical necessity of medical monitoring . . . is an invasion of a legally protected interest" given prior reliance on the Restatement in other contexts. *See* Pls. Objs. Ex. B (ECF No. 2314-2); *see*, *e.g.*, *id.* at A-1–2. But Plaintiffs cite no "clear indication" that Arizona would abandon the traditional manifest physical injury requirement. That Arizona may have relied on other sections of the Restatement in other contexts falls far short of the kind of authority needed to predict a substantive change to state law liability. *City of Phila.*, 994 F.2d at 115, 126–27.

Moreover, Plaintiffs' reliance on Restatement (Second) section 7 is misplaced, even if the jurisdiction has adopted or would adopt it. That section merely explains that "injury" is an

"invasion of any legally protected interest," while "harm" is the "detriment" caused by the invasion for which damages may be awarded. Restatement (Second) § 7, comments a, b. To "maintain an action of tort," the plaintiff must establish an "injury." Id. at comment a. Under the traditional rule in all states, economic expectations are not a "legally protected interest" in tort—such expectations are "legally protected" only by contract.

The Restatement (Third) of Torts: Liability for Economic Harm (2020) provides additional helpful guidance. Section 1 provides, "An actor has no general duty to avoid the unintentional infliction of economic loss on another." Section 7 of the Restatement 3d closes the loop, providing, "Except as provided elsewhere in this Restatement, a claimant cannot recover for economic loss caused by: (a) unintentional injury to another person; or (b) unintentional injury to property in which the claimant has no proprietary interest."

The Restatement, therefore, does not support Plaintiffs' argument; it contradicts it. Restatement (Second) Section 7 provides no support for Plaintiffs' position in any of the Disputed Jurisdictions, and this is particularly true for Arizona, given *Burns's* holding that "subclinical" injury is not "the actual loss or damage to a plaintiff's interest required to sustain a cause of action under generally applicable principles of tort law." 752 P.2d at 30 (quoting *Schweitzer v. Consolidated Rail Corp. (Conrail)*, 758 F.2d 936, 942 (3d Cir. 1985)).

2. Arkansas.

Arkansas adheres to the traditional present physical injury requirement for tort claims. *See Dowty v. Riggs*, 385 S.W. 3d 117, 120–23 (Ark. 2010) (reaffirming the physical injury requirement, explaining the extremely high bar to abandoning it, and refusing to carve an exception for emotional distress suffered by a bystander); *see also Pennebaker v. Furry Feet Retreat, Inc.*, 620 S.W. 3d 879, 881–82 (Ark. Ct. App. 2021) (recognizing Arkansas requires present physical injury to state tort claim). Plaintiffs admit that Arkansas has not specifically addressed whether a

tort claim for medical monitoring can be maintained "without proof of present physical injury," but argue that the Arkansas Supreme Court would allow such a claim based on the same Restatement (Second) Section 7 argument discussed above. Pls. Objs. Ex. B (ECF No. 2314-2).

To the extent Plaintiffs argue that Arkansas would deviate from the manifest physical injury requirement for medical monitoring claims based on *Baker v. Wyeth-Ayerst Lab'ys Div., a Div. of Am. Home Prod. Corp.*, 992 S.W. 2d 797 (Ark. 1999), Plaintiffs are mistaken. *See* ECF No. 2314-3 at 31. *Baker* does not address Arkansas's adherence to the manifest physical injury requirement, it holds that product liability claims—like those asserted here—raise numerous predominance issues that preclude class certification. *Baker's* silence fails to provide the "clear indication" required for this Court to predict an expansion of liability.

3. Colorado.

The District Court recognized that "the analysis of other federal court decisions predicting state law must be somewhat nuanced." Remand Op. at 15. Predictions based on what a state's law should be that are not grounded in state law precedent are not "sufficient to serve as the requisite clear indication of state law." *Id.* Nevertheless, Plaintiffs assert "Colorado would recognize a claim for medical monitoring absent proof of physical injury" based on the district court's prediction in *Cook v. Rockwell Int'l Corp.*, 755 F. Supp. 1468 (D. Colo. 1991) that was followed in *Bell v. 3M Co.*, 344 F. Supp. 3d 1207 (D. Colo. 2018). ECF No. 2314-2 at 10–11.

The Colorado state courts of appeal have yet to address whether the state would permit a medical monitoring claim without present physical injury. The district court's prediction in *Cook* that Colorado would carve an exception to the present physical injury requirement was made thirty years ago, based on an assessment of policy and evolving law at that time. *See Cook*, 755 F. Supp. at 1476–77. The court did not analyze Colorado law or recognize the obligation to make *Erie* predictions against the expansion of liability. When the *Bell* district court revisited the issue, it

recognized that *Cook*'s prediction of an independent Colorado medical monitoring claim rested on Judge Babcock's assessments of policy considerations and of the evolving law at that time. *Bell*, 344 F. Supp. 3d at 1216–17. The court further recognized that Colorado decisions, including decisions subsequent to *Cook*, have refused to abandon the present physical injury requirement in the context of emotional distress claims. *Id.* at 1217–18. In the end, the court concluded that both sides provided plausible interpretations of Colorado law, calling it a "close call," but that "plaintiffs have the stronger argument," particularly in light of "the same policy consideration that swayed Judge Babcock" in *Cook*. *Id.* at 1224.

This Court cannot rely on *Cook* and *Bell* to predict that Colorado would abandon the present physical injury requirement. *Cook* contradicts *Travelers* and *City of Philadelphia* by expanding state tort liability based solely on policy arguments and perceived, decades-old trends in the law without analysis of Colorado law. *Bell* compounds this error, adopting *Cook*'s policy arguments to justify a prediction that the court recognized was not supported by Colorado law or the evolving law at that time in the majority of jurisdictions that had considered the issue, including the U.S. Supreme Court in *Metro-N. Commuter R. Co. v. Buckley*, 521 U.S. 424, 440 (1997). Third Circuit precedent does not allow this Court to "jump[] ahead" of Colorado law to expand tort liability based on policy arguments and a split among courts outside of Colorado, and it does not permit this Court to adopt predictions made by district courts that did so. *See City of Phila.*, 994 F.2d at 125-26, nn.12, 13 (refusing to follow district court predictions from other states).

4. Connecticut.

In *Poce v. O & G Indus., Inc.*, an intermediate state appellate court held that Connecticut tort law requires allegations of present physical injury as an element of liability, without which a claim for medical monitoring costs cannot be stated. 269 A.3d 899, 908–10 (Conn. App. Ct. 2022) (holding claims for medical monitoring require "the pleading and proof of some physical

component of injury"). As an intermediate appellate ruling, *Poce* is "persuasive authority" and "not to be disregarded." *Travelers*, 594 F.3d at 244 (citation omitted).

Nevertheless, Plaintiffs contend that *Doe v. City of Stamford*, 699 A.2d 52, 54 (Conn. 1997) permits the recovery of medical testing and treatment expenses based on exposure to diseases without present physical injury, a result that *Martin v. Shell Oil Co.*, 180 F. Supp. 2d 313, 323 (D. Conn. 2002) purportedly followed. Based on this, Plaintiffs argue that Connecticut would abandon the manifest physical injury requirement. Plaintiffs further assert that their "allegation of subcellular injury is sufficient to satisfy [the] physical harm requirement." Pls. Objs. Ex. B (ECF No. 2314-2) at A-2–3 (citing *Bowerman v. United Illuminating*, 1998 WL 910271, at *5 (Conn. Super. Ct. Dec. 15, 1998)).

Plaintiffs are incorrect. The court in *Stamford* was not interpreting tort law, much less extending it—the court was interpreting the Connecticut Workers Compensation Act, and its holding is limited to the Act's defined term "injury." 699 A.2d at 54–57. The court expressly distinguished this limited analysis from the U.S. Supreme Court's analysis in *Buckley*, where the Court was interpreting FELA, a "statute that is closely tied to traditional tort principles," and held those principles do not recognize medical monitoring costs to constitute actionable injury. *Stamford*, 699 A.2d at 57, n.11. *Martin* declined to extend *Stamford* beyond workers compensation cases as it was unnecessary given the plaintiff's representation that he was not asserting that medical monitoring could be awarded without actual injury. 180 F. Supp. 2d at 323.

Plaintiffs' assertion that subcellular injury constitutes manifest physical injury in Connecticut is without foundation. *Bowerman*, an unpublished trial court decision, did not hold that subcellular or other physiological changes constitute actionable injury. The opposite. It held that "asymptomatic scarring of lung tissue and the implantation of fibers in the lungs due to

asbestos exposure did not constitute detrimental physical harm that was actionable." *Poce v. O & G Indus., Inc.*, 269 A.3d at 909 (discussing *Bowerman* and *Goodall v. United Illuminating*, Superior Court, judicial district of New London, Docket No. X04-CV-95-0115437-S, 1998 WL 914274 (December 15, 1998)). Indeed, *Bowerman* held that "scarring of the lung tissue" and asbestos implantation in the lungs could constitute actionable injury only if presently detrimental to plaintiffs. *Bowerman*, 1998 WL 910271, at *5. Almost twenty years later, another Superior Court held that subclinical physiological changes are not actionable injuries until they manifest into symptoms of an actual disease or illness. *Dougan v. Sikorsky Aircraft Corp.*, No. X03HHDCV126033069S, 2017 WL 7806431, at *4 (Conn. Super. Mar. 28, 2017).

To the extent Plaintiffs contend that *Dougan v. Sikorsky Aircraft Corp.*, 251 A.3d 583 (Conn. 2020) supports their position (ECF No. 2314-3 at 33), they are wrong. There, the court merely "assume[d], without deciding that Connecticut law recognizes a claim for subclinical cellular injury that substantially increased the plaintiffs' risk of cancer and other asbestos related diseases" and then further "assume[ed] without deciding, that the *Donovan* elements govern proof of a medical monitoring claim." *Id.* at 593–94. The court did so to demonstrate that the plaintiffs' claims would fail to meet even that permissible standard. *Id.* at 594. *Dougan* does not provide a clear indication that the Connecticut Supreme Court would deviate from the manifest physical injury requirement, and the District Court cannot jump ahead of that court to predict it would do so here. *See City of Phila.*, 994 F.2d at 125, n.12.

5. Georgia.

"To recover for personal injuries under Georgia law, a plaintiff must show that he has suffered 'injury to life or limb or damage to other property." *Parker v. Wellman*, 230 F. App'x 878, 881 (11th Cir. 2007) (quoting *Pickren v. Pickren*, 593 S.E. 2d 387, 388 (Ga. Ct. App. 2004)). This requirement extends to toxic exposure claims, and requires evidence of "actual disease, pain

or impairment of some kind." *Id.* at 882 (quoting *Boyd v. Orkin Exterminating Co.*, 381 S.E. 2d 295, 298 (Ga. Ct. App. 1989)). Allegations of "subclinical and cellular damage" from exposure do not constitute physical injury until they manifest in "an identifiable physical disease, illness, or impairing symptoms." *Id.* Because the plaintiffs made no such allegations of manifest impairment, the court held that the district court correctly dismissed the claim for medical monitoring. *Id.* at 883. Plaintiffs provide no basis from which to depart from *Parker*'s thorough analysis of Georgia law.

6. Hawaii.

Hawaii's highest court has not directly addressed claims for medical monitoring costs absent allegations of present physical injury. Plaintiffs have identified no authority from any trial court or intermediate appellate court that would permit this Court to predict the state would abandon the present physical injury requirement. In the only relevant opinion, the federal district court in *In re Hawaii Fed. Asbestos Cases*, concluded that Hawaii requires plaintiffs to allege a present physical injury to state a tort cause of action, and that this pleading requirement is not satisfied by allegations of "sub-clinical conditions" that are "unaccompanied by an objectively verifiable functional impairment." 734 F. Supp. 1563, 1567 (D. Haw. 1990). As no basis in state law exists to predict that Hawaii would deviate from the traditional manifest physical injury rule, Plaintiffs' negligence and products liability claims should be dismissed.

7. Idaho.

In Idaho, "there is no tort until there is an injury" that is "objectively ascertainable," which means "objective medical proof would support the existence of an actual injury." *Davis v. Moran*, 735 P.2d 1014, 1019–20 & n.4 (Idaho 1987). Nevertheless, Plaintiffs argue that Idaho would adopt Plaintiffs' "economic loss" argument to permit a tort claim seeking future medical monitoring expenses without present physical injury. Pls. Objs. (ECF No. 2314) at 11 (citing *Davis*, 735 P.2d

at 1019–20 & n.4 and *Hepburn v. Bos. Sci. Corp.*, No. 3:17-CV-00530-DCN, 2018 WL 2275219, at *5 (D. Idaho May 17, 2018)). Plaintiffs' argument is unsupported.

First, *Davis* rejected Plaintiffs' assertion that "the economic loss" of medical monitoring costs satisfies the injury requirement in Idaho. There, the Idaho Supreme Court held that the claim did not accrue upon exposure or even when a physician recommended testing in June 1983; rather, the claim became actionable only when there was an objectively diagnosable injury (*e.g.*, "spinal damage"). *Id.* at 1016, 1020 n.4. Second, *Hepburn*, addressed Article III injury-in-fact standing, not Idaho's manifest physical injury requirement. *Id.* at *3–5. Moreover, Hepburn alleged physical injury: "constant pains in the abdominal region." *Id.* at *1.

8. Illinois.

Claims for medical monitoring require allegations of a manifest physical injury in Illinois. *Berry v. City of Chicago*, 181 N.E. 3d 679, 688-89 (Ill. 2020) (holding claims for medical monitoring require proof of present physical injury, not just a risk of future disease). Plaintiffs, however, insist that Illinois would abandon the manifest physical injury requirement to allow a claim for medical monitoring costs to proceed based solely on economic loss (i.e., the future costs of medical monitoring procedures). Pls. Objs. (ECF No. 2314) at 11–12 (citing *Lewis v. Lead Indus. Ass'n, Inc.*, 793 N.E. 2d 869 (Ill. App. Ct. 2003)). Not so.

Contrary to Plaintiffs' description (Pls. Objs. at 12), the plaintiffs in *Berry* alleged actual exposure to lead, allegations substantiated by water testing and blood samples. 181 N.E. 3d at 683–84. Nevertheless, the Illinois Supreme Court held that the plaintiffs failed to state a claim because none alleged "any physical impairment, dysfunction, or physically disabling consequence" from the exposure. *Id.* at 687. Without "actual or realized harm," the claim devolves into one seeking compensation for the "increased risk of future harm" and risks clogging the "court dockets . . . with comparatively unimportant or trivial claims." *Id.* at 688. The Illinois Supreme

Court rejected the plaintiffs' contention "that the need for medical testing or monitoring" itself is a cognizable injury because it "is simply another way of saying [plaintiffs] have been subjected to an increased risk of harm," which is not an injury. *Id.* at 688–89.

The R&R correctly recognized that dicta regarding risk of harm constituting injury from an intermediate appellate court decision that predates *Berry*, *Lewis v. Lead Industries Ass'n*, *Inc.*, 793 N.E. 2d 869 (Ill. App. Ct. 2003), is insufficient to support a determination that the Illinois Supreme Court would deviate from the manifest physical injury requirement reaffirmed in *Berry*. R&R (ECF No. 2273) at 8 n.6. Additionally, *Lewis* was reversed by the Illinois Supreme Court in *Lewis v. Lead Indus. Ass'n*, 178 N.E. 3d 1046, 1049 (Ill. 2020), and Plaintiffs do not identify any portion of that opinion that would support a prediction that contradicts *Berry*.

9. Indiana.

In *Holiday v. Atl. Richfield Co.*, No. 2:16-cv-525, 2022 WL 4463342, at *4–7 (N.D. Ind. Sept. 23, 2022), the district court determined that Indiana law does not permit the recovery of medical monitoring costs without present physical injury. *Holiday* recognizes that Indiana tort law requires a "compensable injury" as an element of liability. 2022 WL 4463342, at *4 (quoting *Ryan v. TCI Architects/Engineers/Contractors, Inc.*, 72 N.E. 3d 908, 913 (Ind. 2017)). Under Indiana law, "a cause of action accrues only when a current diagnosable illness develops"—not when "exposure results in physical change, or so called 'subclinical injury." *Id.* (citing *AlliedSignal, Inc. v. Ott*, 785 N.E. 2d 1068, 1075 (Ind. 2003)). The district court correctly recognized this to be "a strong indicator of the Indiana Supreme Court's view of the requirement of present physical injury in a tort case" and rejected the plaintiffs' call for a prediction to expand tort liability by recognizing risk of injury to constitute physical injury itself. *Id.* at *4–5.

Plaintiffs nevertheless assert that Indiana would abandon the manifest physical injury requirement to allow a claim for medical monitoring costs to proceed based solely on economic

loss (*i.e.*, the future costs of medical monitoring procedures). Plaintiffs base this assertion on the prediction in *In re Zantac (Ranitidine) Products Liability Litigation*, 546 F. Supp. 3d 1152, 1166 (S.D. Fla. 2021) "that the Indiana Supreme Court would recognize medical monitoring as a form of damages for negligence claims." ECF No. 2314-1 at A-7.

The Zantac court did not have the benefit of the Holiday court's analysis, and the decision fails to discuss the important Indiana precedent analyzed in Holiday, including AlliedSignal. Zantac instead relies on Gray v. Westinghouse Electric Corp., 624 N.E. 2d 49, 54 (Ind. Ct. App. 1993) and Allgood v. General Motors Corp., No. 102CV1077DFHTAB, 2005 WL 2218371, at *7 (S.D. Ind. Sept. 12, 2005) to conclude that Indiana tort law, particularly negligence, does not require a present physical injury to recover medical monitoring costs. 546 F. Supp. 3d at 1166-67. Allgood relies entirely on Gray to predict medical monitoring costs are recoverable through a nuisance claim without present physical injury. 2005 WL 2218371, at *8. Gray held that this is because nuisance claims are unique in that they arise from a statute that does not require "physical damage to person or property." 624 N.E. 2d at 54. Plaintiffs do not assert a nuisance claim here, and neither decision supports their argument, let alone provides the "clear indication" necessary for the District Court to predict an expansion of Indiana tort liability.

10. **Iowa.**

The Iowa Supreme Court has given no indication that it would permit plaintiffs to seek medical monitoring relief without alleging a manifest physical injury. In *Pickrell v. Sorin Group USA, Inc.*, 293 F. Supp. 3d 865, 868 (S.D. Iowa 2018), the court considered an asymptomatic plaintiff's exposure claims caused by an alleged defect in a blood temperature regulating machine, seeking medical monitoring costs. *Pickrell* recognized that claims sounding in negligence require actual injury in Iowa. *Pickrell*, 293 F. Supp. 3d at 868 (citing *Vossoughi v. Polaschek*, 859 N.W. 2d 643, 649–50 (Iowa 2015)); *Niblo v. Parr Mfg., Inc.*, 445 N.W. 2d 351, 354 (Iowa 1989). Mere

exposure creating a need for medical testing does not establish a "compensable injury." *Slaymaker v. Archer-Daniels-Midland Co.*, 540 N.W. 2d 459, 460–61 (Iowa Ct. App. 1995) (persons exposed to asbestos necessitating testing that revealed no "significant damage" did not suffer physical injury). *Pickrell*, therefore, correctly predicted that the Iowa Supreme Court would not permit a claim for medical monitoring costs absent physical injury. 293 F. Supp. 3d at 868.

Plaintiffs fail to identify any basis to depart from *Pickrell* and its well-founded analysis—let alone sufficient justification to "jum[p] ahead" of Iowa law to predict an expansion of tort liability. *City of Phila.*, 994 F.2d at 125–26, n.12.

11. Kansas.

Kansas's courts have not addressed whether medical monitoring costs may be recovered absent present physical injury. They have, however, long held that claims for damages caused by the risk of future injury must have arisen from a physical injury. *Reynolds v. Highland Manor, Inc.*, 954 P.2d 11, 13 (Kan. Ct. App. 1998) (applying rule in the context of a claim for emotional damages). Plaintiffs' attempt to distinguish this decision on the facts misses the point. Pls. Objs. (ECF No. 2314) at 13, n.15. The Court here must opt for the conservative interpretation of state law that does not expand liability. *Reynolds* helps the court in fulfilling that burden by showing how a Kansas intermediate appellate court approached a related issue.

To the extent Plaintiffs assert that *Burton v. R.J. Reynolds Tobacco Co.*, 884 F. Supp. 1515 (D. Kan. 1995), interpreted Kansas law as carving an exception to this rule for medical monitoring damages, they are wrong. Pls. Objs. (ECF No. 2314) at 12–13. *Burton* held that medical monitoring costs were recoverable as a component of damages only if the plaintiff proves the elements of liability, including physical injury. *Burton*, 884 F. Supp. at 1523; *see also Duncan v. Nw. Airlines, Inc.*, 203 F.R.D. 601, 607–08 (W.D. Wash. 2001) (recognizing this to be *Burton*'s holding); *Witherspoon v. Philip Morris Inc.*, 964 F. Supp. 455, 467 (D.D.C. 1997) (same). Where

Kansas has permitted the recovery of medical monitoring costs, it does so only where those costs "arose from an existing injury," as in *Cott. Burton*, 884 F. Supp. at 1523, n.6 (citing *Cott v. Peppermint Twist Mgmt. Co.*, 856 P.2d 906 (Kan. 1993)).

12. Maine.

In *Higgins v. Huhtamaki, Inc.*, No. 1:21-cv-00369, 2022 WL 2274876, at *10 (D. Me. June 23, 2022), the court held that in Maine "[t]here is generally no cause of action in tort until a plaintiff has suffered an identifiable, compensable injury." *Id.* (quoting *Bernier v. Raymark Indus., Inc.*, 516 A.2d 534, 542 (Me. 1986)). "So, a plaintiff who is exposed to an environmental toxin does not have a judicially recognizable claim 'until there has been a manifestation of physical injury sufficient to cause him actual loss, damage or suffering." *Id.*

Plaintiffs' attempt to distinguish and minimize *Higgins* misrepresents the decision and its thorough review of Maine law in the context of exposure-related tort claims. Pls. Objs. Ex. B at A-8–9. First, *Higgins* considered both a stand-alone medical monitoring claim and medical monitoring costs as a remedy. 2022 WL 2274876, at *10–11. Second, *Higgins* recognized that the Maine Supreme Court unequivocally held in *Bernier* that the plaintiffs had to prove identifiable injury—mere microscopic injury from inhalation is insufficient. *Id.* at *11 (quoting *Bernier*, 516 A.2d at 543). *Higgins*, therefore, rejected any assertion that alleged exposure and need for medical monitoring constitute "compensable injury" under Maine law. Third, applicability of *Bernier*'s holding is not limited to issues of accrual of claims under 14 Maine Revised Statutes Annotated Section 221. Rather, the issue required the court to examine Maine tort law generally, and the court held: (1) a tort cause of action requires "identifiable, compensable injury"; (2) threat of unrealized future harm "is not enough"; (3) the actionable harm in a latent exposure case is "the manifestation of disease in the body"; and (4) "subclinical injury" is not actionable harm. *Bernier*, 516 A.2d at 542-43.

Plaintiffs offer no basis from which to conclude that *Higgins*'s analysis of Maine law is wrong, let alone grounds that would permit this Court to expand Maine tort liability by predicting it would abandon the physical injury requirement here.

13. Minnesota.

The Minnesota Supreme Court has given no indication that it would permit plaintiffs to state a claim for medical monitoring damages absent allegations of a manifest physical injury. In Minnesota, "damage is an essential element of a negligence cause of action" that is not satisfied by allegations of a mere "threat of future harm." *Reliance Ins. Co. v. Arneson*, 322 N.W. 2d 604, 607 (Minn. 1982). Accordingly, "Minnesota does not recognize" torts based on "a claim of increased risk of cancer." *Woyke v. Tonka Corp.*, 420 N.W. 2d 624, 625–26 (Minn. Ct. App. 1988). Consistent Minnesota precedents are thus inconsistent with any prediction that the Minnesota Supreme Court would abandon the manifest physical injury requirement.

Plaintiffs focus on *Bryson v. Pillsbury Co.*, 573 N.W. 2d 718, 721 (Minn. Ct. App. 1998), an intermediate appellate court decision that they claim shows that Minnesota permits claims for medical monitoring without proof of present physical injury. Pls. Objs. (ECF No. 2314) at 14. Plaintiffs misstate *Bryson's* holding. In fact, *Bryson* held that claims seeking medical monitoring require allegations of a "present injury." 573 N.W. 2d at 720–21.

The question in *Bryson* was whether alleged "chromosome damage" constitutes an allegation of a "real and present physical and biologic injury," which in that case presented a question of fact as to whether the alleged damage resulted in any present detrimental physical impact. *Id.* at 721. *Bryson* did not hold that "latent" subcellular or other physiological change—which is what Plaintiffs allege here (MMSAC ¶ 384)—meets this requirement. Plaintiffs accordingly plead only a threat of future harm, which is not a present physical injury under Minnesota law and fails to state a claim.

14. Montana.

Montana requires present physical injury to state a tort cause of action and holds that exposure alone is insufficient to satisfy the element. *See Schelske v. Creative Nail Design, Inc.*, 933 P.2d 799, 803–04 (Mont. 1997) (explaining physical harm is an element of exposure claims arising from alleged product defect and requiring Plaintiff to identify specific injuries/illnesses caused by alleged toxic exposure). The Montana Supreme Court has given no indication that it would deviate from the manifest physical injury requirement to permit no-injury medical monitoring claims.

Plaintiffs nevertheless argue that *Lamping v Am. Home Prods.*, No. DV-97-85786, 2000 WL 35751402 (Mont. Dist. Ct. Feb. 2, 2000) provides sufficient basis to predict that Montana would abandon that requirement here to create an independent medical monitoring cause of action. Pls. Objs. (ECF No. 2314) at 13. *Lamping* is an unpublished, trial-level decision, that was expressly limited to its facts, and has never been cited in any other Montana case. *Lamping* provides no basis to predict that the Montana Supreme Court would enact a dramatic change to state tort law. *City of Phila.*, 994 F.2d at 125 (holding a lone trial court decision "is insufficient").

Plaintiffs also contend that *Lindsay Drilling & Contracting v. U.S. Fidelity & Guaranty Co.*, 676 P.2d 203, 206 (Mont. 1984) supports the conclusion that the term "injury" does not necessarily contemplate harm, but rather may be "a physical change or alteration which is either beneficial, detrimental or of no consequence." Pls. Objs. Ex. B (ECF No. 2314-2) at A-10. This argument ignores the fact that in *Lindsay Drilling* the Montana Supreme Court was not analyzing the elements of a tort claim but instead was interpreting an insurance policy's use of the term "injury." 676 P.2d 203, 205–06. And even there, the court held that the insurance policy required loss or detriment—*i.e.*, "harm"—not mere "physical change or alteration." *Id.* at 205.

15. Nebraska.

While Nebraska courts have yet to address medical monitoring, it is well settled that Nebraska adheres to the manifest physical injury requirement for negligence claims. *Avila v. CNH Am. LLC*, No. 4:04-cv-03384, 2007 WL 2688613, at *1 (D. Neb. Sept. 10, 2007) ("damages are an essential element" under Nebraska law and relief cannot be provided absent "present physical injury"). As explained in *Ward v. City of Alliance*, 417 N.W. 2d 327 (Neb. 1988), toxic exposure claims accrue only after the injury "manifest[s]" itself. *Id.* at 328, 330. Accordingly, and given the obligation not to expand state tort law in making *Erie* predictions, this Court should predict that Nebraska would require present physical injury to state a claim for medical monitoring costs. *See, e.g., Trimble v. Asarco, Inc.*, 232 F.3d 946, 962–63 (8th Cir. 2000) (holding Nebraska law has not recognized a cause of action for medical monitoring absent "present physical injury" and declining to expand substantive liability under Nebraska law to do so) *abrogated on other grounds by Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546 (2005). Plaintiffs identify no basis for concluding otherwise.

16. New Mexico.

The New Mexico Supreme Court has given no indication that it would deviate from the manifest physical injury requirement to permit no-injury claims for medical monitoring. *Sanchez v. Clayton*, 877 P.2d 567, 573 (N.M. 1994) ("[L]iability does not attach to negligent acts that do not result in actual harm or damage.") Nevertheless, Plaintiffs urge the Court to predict that New Mexico would do so because the costs they allege for "diagnostic testing for the early detection of disease" are an actionable harm. Pls. Objs. Ex. B (ECF No. 2314-2) at A-12. Plaintiffs contend that their position is supported by *Lovelace Medical Center v. Mendez*, 805 P.2d 603, 609–10 (N.M. 1991), which they claim recognized that "harm includes detriment to pecuniary advantage and that economic loss [w]as recoverable injury for tort." Pls. Objs. Ex. B (ECF No. 2314-2) at

A-12. But *Lovelace* addresses a unique medical malpractice situation and has nothing to do with the facts alleged here. It is not authority that would support a prediction that New Mexico would abandon the manifest physical injury requirement here.

Furthermore, New Mexico has adopted the RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR ECONOMIC HARM § 1, which establishes that there is generally no duty "to avoid the unintentional infliction of economic loss." *Nat. Roofing, Inc. v. Alstate Steel, Inc.*, 366 P.3d 276, 278 (N.M. Ct. App. 2015). Section 3 of the same Restatement recognizes an exception to this rule for medical malpractice actions, where there are inherent limits to the liability imposed and there is an information imbalance. *See* RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR ECONOMIC HARM § 1 *comment d. Lovelace* falls into this unique exception and has been so limited. *See Provencio v. Wenrich*, 261 P.3d 1089, 1096–97 (N.M. 2011) (limiting *Mendez* to when a doctor botches a sterilization, does not disclose the failure, and the patient has a child causing parents to incur economic loss from raising the child).

Here, Plaintiffs are not alleging professional negligence. Rather, they allege exposure "which may, in the future lead to an injury," for which they seek compensation—specifically, the costs of lifelong testing to assuage those fears, an economic loss. In *Alberts v. Schultz*, the New Mexico Supreme Court disapproved of such claims, indicating they are not cognizable in the absence of physical injury. 975 P.2d 1279, 1285 (N.M. 1999).

17. New York.

Plaintiffs acknowledge that New York requires "the physical manifestation of or clinically demonstrable presence of toxins in the plaintiff's body" to state a claim to recover future medical monitoring expenses. Pls. Objs. (ECF No. 2314) at 14–15; *Benoit v. Saint-Gobain Performance Plastics Corp.*, 959 F.3d 491, 501–02 (2d Cir. 2020) (interpreting New York law as expressly requiring "physical injury" to state a personal injury claim, including a claim for the "costs of

medical monitoring"); *Caronia v. Philip Morris USA, Inc.*, 5 N.E. 3d 11, 16–17 (N.Y. 2013) (holding New York would not permit a claim where the "only 'injury' is the 'financial burden associated with periodic medical monitoring").

Plaintiffs argue that their assertions of "subcellular or other physiological change" are sufficient. Pls. Objs. (ECF No. 2314) at 14–15. *Caronia* rejected this argument. 5 N.E. 3d 11, 17–18. The question, therefore, is whether Plaintiffs have plausibly alleged that each of them has a clinically demonstrable presence of toxins in their body or a physical manifestation of toxin contamination. The *Benoit* plaintiffs met this standard by alleging blood test results. 959 F.3d at 501–02. Plaintiffs here identify no such allegation in the MMSAC, which contains no Plaintiffspecific allegations of injury.

18. **Ohio.**

The District Court recognized that "the analysis of other federal court decisions predicting state law must be somewhat nuanced." Remand Op. at 15. Nevertheless, Plaintiffs urge the Court to predict Ohio would abandon the present physical injury requirement for a medical monitoring claim based on the federal district court's prediction in *Day v. NLO*, 851 F. Supp. 869, 879–82 (S.D. Ohio 1994). Pls. Objs. (ECF No. 2314) at 13. As the District Court explained in the Remand Opinion, it cannot predict an expansion of state tort liability based on a prediction made by a federal district court that is not grounded in state law and defies the obligation to make conservative *Erie* predictions against expanding state tort liability. Remand Op. at 15. *Day* falls into this camp and should not be followed.

In *Day*, the federal district court recognized: (1) asymptomatic claims for future medical monitoring costs seek to recover based "on the chance that an injury has been sustained"; and (2) Ohio does not allow claims based on the "risk of disease" as opposed to a present injury. 851 F. Supp. at 879. Nevertheless, the district court declared: "if the Plaintiffs can establish liability and

an increased risk of disease, they will be entitled to medical monitoring." *Id.* at 881. While it is not clear whether the district court was making an *Erie* prediction or simply believed it was entitled to create state law, the court predicated this expansion of tort liability on (1) decisions in other courts (D.C., Utah, and California) and (2) a belief that it was in the interest of public policy. *Id.* at 880–81. What is clear is that *Day*'s declaration was not supported by any Ohio precedent. It was in spite of it, admittedly. *Day*'s prediction thus provides no basis upon which to predict an expansion of Ohio tort liability.

As explained in *Riston v. Butler*, 777 N.E. 2d 857, 866 (Ohio Ct. App. 2002), Ohio courts have not addressed whether Ohio law permits claims for medical monitoring arising solely from exposure without present physical injury. Plaintiffs do not dispute *Riston*'s assessment that permitting such a claim would require "a change in Ohio law." *Id.* Indeed, Plaintiffs admit that Ohio does not permit recovery of economic losses if such losses do not arise from "tangible physical injury to persons" or property under *Queen City Terminals, Inc. v. Gen. Am. Transp. Corp.*, 653 N.E. 2d 661, 667 (Ohio 1995). Pls. Objs. Ex. B (ECF No. 2314-2) at A-14. And they admit that the future costs of the medical monitoring sought here are "economic losses." *Id.*

Plaintiffs instead argue that the need to incur those costs is caused by "damage to Plaintiffs' property, their Devices." *Id.* Plaintiffs offer no clarification on the nature of this "damage" or its purported causal connection to the alleged need to incur medical monitoring costs. Nor is any connection apparent, given the lack of Plaintiff-specific allegations of device damage, let alone Plaintiff-specific allegations of physical injury, causing any need for medical treatment, including any medical testing.

In sum, Plaintiffs' claims based solely on the risk of past exposure allegedly increasing the risk of future disease and the need for medical testing are not cognizable under Ohio law, and there

is no "clear indication" that the Ohio Supreme Court would expand liability for such claims.

19. Oklahoma.

In *Reece v. AES Corp.*, the Tenth Circuit reviewed Oklahoma law and held that Oklahoma adheres to the manifest physical injury requirement. 638 F. App'x. 755, 775–76 (10th Cir. 2016). *Reece* then rejected arguments (1) that concern about future risk constitute cognizable injury and (2) that the formulaic listing of conditions consistent with exposure sufficed to plausibly allege cognizable physical injury. *Id.* at 776–78. Similarly, in *McCormick v. Halliburton Co.*, 895 F. Supp. 2d 1152, 1157–59 (W.D. Okla. 2012), the court recognized the injury requirement and rejected the plaintiffs' argument that it was satisfied by future "monetary losses" from medical monitoring costs, explaining that the plaintiffs were conflating "injury" with "damages." *See also Taylor v. Michelin North America, Inc.*, No. 14-CV-293, 2018 WL 1569495, at *6 (N.D. Okla. Mar. 30, 2018) (medical monitoring claim dismissed where "plaintiffs have not yet presented evidence of physical injuries attributable to contaminants"). Plaintiffs provide no basis from which the District Court could depart from these decisions to predict that Oklahoma would abandon the manifest physical injury requirement here.

20. Oregon.

In *Lowe v. Philip Morris USA, Inc.*, the plaintiff, who did not allege "present physical harm," asserted negligence claims based on allegations that the manufacture and sale of cigarettes caused her to have a "significantly increased risk" of cancer and, as a result, "it was 'reasonable and necessary' for her to undergo 'periodic medical screening." 183 P.3d 181, 182–83 (Or. 2008). The Oregon Supreme Court affirmed the dismissal of the complaint because Oregon requires manifest physical injury. In reaching this decision, the court expressly rejected arguments that a viable claim could be based on: (1) the significantly increased risk of cancer itself; or (2) "the economic cost" of medical monitoring. *Id.* at 184.

"[A] plaintiff must suffer harm 'to an interest of a kind the law protects against negligent invasion" to state a claim. *Id*. The mere threat of physical harm is insufficient to constitute an actionable injury. *See id*. The threat only becomes actionable when it manifests into "present physical harm." *See id*. at 185. The court also held Plaintiffs' second argument contradicted Oregon law because the costs of medical monitoring are economic losses that are not actionable absent a special duty or physical injury to person or property. *See id*. at 186.

Justice Walters's concurrence agreed that the claim failed because there was no alleged "present physical harm." *Id.* at 187. She then clarified that physical harm should include "detectable physical effects" from negligent exposure to a harmful substance. *Id.* at 188. Nevertheless, she concurred in the result: simply alleging the exposure that comes with smoking a pack every day for five years does not establish the necessary physical harm to state a claim.

Accordingly, *Lowe* forecloses any assertion that the economic loss of future medical monitoring costs or mere physiological change that has yet to manifest in physical harm constitute actionable injury for the negligence or products liability claims Plaintiffs assert under Oregon law.

21. Puerto Rico.

Plaintiffs do not dispute that Puerto Rican tort law requires proof of actual damages to state a viable claim. Pls. Objs. Ex. B at A-15–16. Instead, they argue that Puerto Rico would adopt Restatement (Second) of Torts Section 7 and because of this, would hold the "economic loss" of the alleged future need to incur medical monitoring costs satisfies the actual damage requirement. *Id.* Section 7, however, merely defines injury to constitute the invasion of a "legally protected interest," and there is "no general duty to avoid the unintentional infliction of economic loss on another." RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR ECONOMIC HARM § 1; *Isla Nena Air Servs., Inc. v. Cessna Aircraft Co.*, 449 F.3d 85, 90–92 (1st Cir. 2006) (predicting Puerto Rico would require injury to person or property to state a products liability claim). Plaintiffs do not

identify any authority that would permit this Court to predict Puerto Rico would expand liability to permit claims premised on the risk of exposure that may increase the risk of a future disease and/or the future incurrence of the economic loss of medical monitoring costs. Nor do they provide any basis from which to conclude that allegations of subcellular or other physiological change constitute actionable damage under Puerto Rico law.

22. Rhode Island.

In Rhode Island, "the possibility of contracting cancer resulting from mere exposure to a carcinogen, although potentially increasing one's risk of developing cancer, is too tenuous to be a viable cause of action." *Kelley v. Cowesett Hills Assocs.*, 768 A.2d 425, 430 (R.I. 2001). Thus, "in the absence of physical manifestation" (*i.e.*, "symptomatology"), a plaintiff cannot "establish a *prima facie* case of negligence as a matter of law." *Id.* at 430, 431. Plaintiffs' attempt to characterize *Kelley*'s holding as being limited to claims for emotional distress ignores the plain language of the holding. The Rhode Island Superior Court recognized this in *Miranda v. Dacruz*, No. PC04-2210, 2009 WL 3515196, at *7–8 (R.I. Super. Ct. Oct. 26, 2009), holding an asymptomatic plaintiff cannot assert a claim for medical monitoring costs under *Kelley*.

Plaintiffs cite no authority that would permit this Court to predict that Rhode Island's highest court would reverse course from *Kelley* and permit claims for medical monitoring absent allegations of a physical manifestation of disease or illness. *Kelley* plainly rejected the argument that freedom from exposure to harmful substances is a legally protected interest. Further, the RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR ECONOMIC HARM § 1 and *Miranda* support the conclusion that freedom from economic loss, including costs associated with medical monitoring, is not a legally protected interest, and Plaintiffs cite no case to the contrary. In the lone substantive decision Plaintiffs reference, *Emerson v. Magendantz*, 689 A.2d 409, 413–14 (R.I. 1997), the plaintiff *did* suffer physical harm, including the pains of delivery and an "additional invasive

medical treatment," and the court *rejected* recovery of economic losses, namely the costs of rearing the child to adulthood, as a viable independent basis for a claim. Plaintiffs' assertions to the contrary are unsupported and mistaken. Pls. Objs. Ex. B (ECF No. 2314-2) at A-16.

23. South Carolina.

The South Carolina Supreme Court has given no indication that it would depart from the traditional manifest physical injury requirement. In the only on-point case, a federal district court predicted that South Carolina would not permit a stand-alone medical monitoring claim, and that medical monitoring costs would potentially be recoverable only if liability were established under another tort claim. *Rosmer v. Pfizer, Inc.*, No. CIV.A. 9:99-228018RB, 2001 WL 34010613, at *5 (D.S.C. Mar. 30, 2001). Plaintiffs identify no other authority considering South Carolina law that reaches a different conclusion or provides a basis to predict that South Carolina's highest court would disagree and enact a dramatic change to existing tort law.

Moreover, it is well established in South Carolina that where, as here, a plaintiff asserts liability arising from an alleged product defect, South Carolina law provides no remedy absent "physical harm to person or property" other than the product. *Sapp v. Ford Motor Co.*, 687 S.E. 2d 47, 49–50 (S.C. 2009); S.C. Code Ann. § 15-73-10 (product defect damages are limited to "physical harm"). Plaintiffs here allege they "have suffered property damage" but do not identify damage to property other than their devices. ECF No. 2314-2 at A-16. Nor have Plaintiffs identified any basis from which to find that their conclusory allegations of "latent" subcellular or other physiological change satisfy South Carolina's "physical harm" requirement. To the extent Plaintiffs argue that this requirement does not apply to products posing serious risk of physical harm, Pls. Objs. Ex. B (ECF No. 2314-2) at A-16, *Sapp* held that this exception applies only to residential houses. *Sapp*, 687 S.E. 2d at 50.

24. Tennessee.

The R&R recommended denying the motion to dismiss claims for medical monitoring under Tennessee law based upon the conclusion that Tennessee does not require Plaintiffs to allege present physical injury to state a claim for medical monitoring. R&R at 9 n. 11. This recommendation is premised on a misreading of *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 575 (6th Cir. 2005) and on remand should be revisited.

In Tennessee, "cognizable damage" is necessary for a claim, and where the claim arises from the risk of future injury, "there must be a reasonable degree of medical certainty that the plaintiff will develop a disease in the future as a result of the injury." *Potts v. Celotex Corp.*, 796 S.W. 2d 678, 681 (Tenn. 1990). Consequently, a claim arising from a latent disease caused by toxin exposure does not exist "until that condition [is] diagnosed, or reasonably could [be] diagnosed." *Id.* at 684. Reviewing and applying Tennessee precedent, *Jones v. Brush Wellman, Inc.*, No. 1:00 CV 0777, 2000 WL 33727733, at *8 (N.D. Ohio, Sept. 13, 2000) held that Tennessee requires "present injury or loss to maintain an action" to recover the costs of "testing for the development of a possible future injury." 2000 WL 33727733, at *8.

Sutton did not hold otherwise. Rather, the court held that an increased risk of future harm suffices for Article III standing. The court expressly declined to reach the issue of whether Tennessee would allow a claim for medical monitoring without manifested physical injury. Sutton, 419 F.3d at 575–76. Neither Sutton's dicta discussion of Tennessee's "murky" law in footnote 7 nor the cases it cites in that footnote provide sufficient grounds for this Court to make an Erie prediction that would expand liability to permit recovery without present physical injury. 419 F.3d at 576, n.7 (citing Laxton v. Orkin Exterminating Co., Inc., 639 S.W. 2d 431 (Tenn. 1982) and Newsom v. Markus, 588 S.W. 2d 883, 887 (Tenn. App. 1979)).

First, Sutton did not address Potts, which as shown above is critical to the analysis of

relevant Tennessee law. Second, neither *Newsom* nor *Laxton* held that a plaintiff could recover the costs of a lifetime of future medical monitoring based solely on the risk of exposure to a possible carcinogen without any present injury. *Newsom* is a car accident case in which the plaintiff was not only injured but "totally temporarily disabled at the time of the collision" and the court merely held that verdicts were not impermissibly inconsistent. *Newsom*, 588 S.W. 2d at 884–88. *Laxton* held that a plaintiff who ingests toxins may recover damages for the mental anguish between discovery of the ingestion and a negative diagnosis but was silent on the issue of medical monitoring damages. 639 S.W. 2d 433–34; *see Jones*, 2000 WL 33727733, at *6 (analyzing *Laxton* and other Tennessee precedent and concluding they do not permit medical monitoring costs without present injury); *see also Camper v. Minor*, 915 S.W. 2d 437, 445–46 (Tenn. 1996) (recognizing that *Laxton* questionably departed from the strict interpretation of the physical manifestation rule, which the court then abandoned as an element for the recovery of damages for severe mental anguish, but otherwise retained).

Following *Sutton*, the Tennessee Supreme Court examined the requirements for recovering future medical expenses in *Rye v. Women's Care Ctr. of Memphis, MPLLC*, 477 S.W. 3d 235, 266 (Tenn. 2015). There, the court reaffirmed the need to prove a physical injury to state a claim for future medical expenses. *Id.* (assuming, but not deciding, that RH-sensitization was a cognizable physical injury before concluding that Rye failed to prove a need for future medical care to reasonable medical certainty).

In the absence of authority from the state's highest court, district courts may not interpret state law in a manner that expands liability under state law. *Travelers*, 594 F.3d at 253 (applying "the well-established principle that where two competing yet sensible interpretations of state law exist, we should opt for the interpretation that restricts liability, rather than expands it, until the

[state's highest court] decides differently.") (cleaned up). Tennessee has long recognized that a present physical injury is a prerequisite to a claim for relief. *E.g.*, *Potts*, 796 S.W. 2d at 681, 684; *Rye*, 477 S.W. 3d at 266. Because Tennessee's highest court has not adopted a different rule, *Travelers* requires this Court to opt for the prediction that Tennessee would adhere to the traditional rule and require Plaintiffs to allege a present physical injury to state a claim for medical monitoring relief.

25. Texas.

The Texas Supreme Court has never indicated that it would deviate from the traditional manifest physical injury requirement to permit no-injury medical monitoring claims. In the absence of applicable Texas precedent, the Court's *Erie* analysis may properly focus on precedent in related areas. *Travelers*, 594 F.3d at 244. Applying this approach, the district court in *Norwood v. Raytheon Co.*, 414 F. Supp. 2d 659, 663–66 (W.D. Tex. 2006) looked to analogous precedent from the Texas Supreme Court in *Temple-Inland Forest Products Corp. v. Carter*, 993 S.W. 2d 88 (Tex. 1999), where the court rejected claims seeking to recover damages for mental anguish arising from the risk of future disease. Based on this decision, the district court in *Norwood* predicted that Texas also would require plaintiffs to allege a manifest physical injury to state a claim for medical monitoring costs. 414 F. Supp. 2d at 662–68. Plaintiffs identify no basis for this Court to reach any different conclusion. Pls. Objs. Ex. B (ECF No. 2314-2) at A-18.

26. Virginia.

Virginia's highest court has not addressed whether plaintiffs may state a claim for medical monitoring costs without alleging a manifest physical injury, but *Ball v. Joy Tech., Inc.*, 958 F.2d 36 (4th Cir. 1991) and *In re All Pending Chinese Drywall Cases*, 80 Va. Cir. 69, 2010 WL 7378659 (Va. Cir. Ct. Mar. 29, 2010) squarely addressed the question presented here. *Ball* determined that Virginia law requires present physical injury. 958 F.2d at 39. And *In re Chinese Drywall*

reaffirmed that conclusion ten years later, holding that "plaintiffs not presently claiming personal injuries" could not seek medical monitoring costs as damages because, while other states have permitted such a claim, Virginia has not, and adopting such a novel claim required the court to impermissibly depart from Virginia common law. 2010 WL 7378659, at *9–10. Plaintiffs identify no contrary authority, much less authority sufficiently authoritative to predict that Virginia's Supreme Court would enact an expansion of state tort law. Nor have Plaintiffs provided any basis to find that their conclusory assertions of subcellular change constitute physical injury under Virginia law, particularly given the holding in *Lo v. Burke* that the cellular growth of a cyst is not an actionable injury until it turns malignant. 455 S.E. 2d 9, 13 (Va. 1995).

27. Washington.

Washington's highest court has not addressed the question whether plaintiffs may assert a claim for medical monitoring damages absent allegations of manifest physical injury, and has given no indication that it would be open to abandoning the traditional manifest physical injury requirement. Looking to federal courts applying Washington law and intermediate appellate court decisions reinforces the conclusion that no-injury medical monitoring claims are not cognizable in Washington. Washington tort law requires "a present, existing injury" to allege tort liability. *Duncan v. Nw. Airlines, Inc.*, 203 F.R.D. 601, 606 (W.D. Wash. 2001) (citing *Koker v. Armstrong Cork, Inc.*, 804 P.2d 659, 668–69 (Wash. Ct. App. 1991); *Sorenson v. Raymark Indus., Inc.*, 756 P.2d 740, 741–42 (Wash. Ct. App. 1988)). "An enhanced risk of disease alone is not enough." *Duncan*, 203 F.R.D. at 606 (citing *Koker*, 804 P.2d at 669). On this basis, the federal court in *Duncan* court held that the "elements of negligence are clear in Washington," and apply to claims seeking medical monitoring costs and require allegations of an existing injury. *Id.* at 609.

IV. CONCLUSION AND ROADMAP FOR DISMISSAL

For all the foregoing reasons, and as set out with particularity above and in the detailed survey of state law precedents, Respironics proposes the following "roadmap for a ruling on the motion to dismiss which identifies, for each count and each state, the claims that will survive" and those that should be dismissed. Remand Op. at 19.

Because the District Court has already expressed that principles warranting the dismissal of claims asserted in the PIAC should be "consistently applied" to overlapping claims in the MMSAC, and has directed the parties to "meet and confer to accomplish the consistent dismissal of overlapping claims after the resolution of any motions to dismiss the contemplated amended Master PI Complaint," Remand Op. at 12-13, the roadmap below omits certain grounds supporting dismissal that apply equally to both the claims in the MMSAC and the claims in the PIAC and/or Second Amended Master Personal Injury Complaint.

CLAIMS THAT SHOULD BE DISMISSED ²⁰			
Claim	Reason for	States	Plaintiffs Asserting Claims
	Dismissal		Under Laws of These States
	Failure to allege manifest physical injury	AZ, AR, CO,	Sean Purdy (AZ), Russell Autry
		CT, DE, GA,	(AZ), Patrick Nielson (CA, OR),
		HI, ID, IL, IN,	Sylvia McDaniel (CO), Jim
		IA, KS, ME,	Wolff (CO), Jill Leavenworth
Nagliagnas (Caunt I)		MN, MT, NE,	(CT), Jose Toscano (CT), Jeffrey
Negligence (Count I)		NH, NJ, NM,	Boyle (DE), Brian McCarty (HI,
		NY, NC, OH,	IL), Michael Wheeler (ID),
		OK, OR, PR,	Danny Baran (IL), Debra Wilson
		RI, SC, TN,	(IL), Michael Dusza (IN), Steve
		TX, VA, WA	Abarr (IA), Sharon Cathers (KS),

²⁰ This Roadmap is presented without prejudice to, and without waiving, Respironics' argument that the entire MMSAC should be dismissed for failure to allege all of the required elements of a claim for medical monitoring relief. *See* Motion to Dismiss, ECF No. 1351, and supporting Memorandum of Law ("MOL"), ECF No. 1352; Reply, ECF No. 1828. The Roadmap presents the claims that are subject to dismissal under the framework of the Remand Opinion.

			Andrew Fisher (GA, MO), Doris Margoles (ME), Prinna Boudreau (MN), Danny David (MT), Boniface Mills (NE), Christopher Glaub (NE), Sabrina Malone (NH, TX), Aaron Taylor (NJ), Joe David Dennett (NM), Beth Rodgers (NM, VA), Hugo Barragan (NY), Sonia Diaz (NY, SC), Bruce Ginsberg (NY), Jeffrey Bartalo (NC), Deana King (NC), Rachel Hock (OH), Chad Wells (OK), Antonio Perez Bonano (PR), Diane Lamontagne (RI), Stephen Flannery (SC), Susan Bakaitis (TN), Jeffrey Kemp (TN), Sarah Claunch (TX), Paul Panzera (TX), Madaline Harbor (VA), Elizabeth Heilman (VA),
Negligence Per Se (Count II)	Failure to allege manifest physical injury	AZ, AR, CO, CT, DE, GA, HI, ID, IL, IN, IA, KS, ME, MN, MT, NE, NH, NJ, NM, NY, NC, OH, OK, OR, PR, RI, SC, TN, TX, VA, WA	Cameron Rose (VA), Jose Lopez (WA), and Robert Peebles (WA) Sean Purdy (AZ), Russell Autry (AZ), Patrick Nielson (CA, OR), Sylvia McDaniel (CO), Jim Wolff (CO), Jill Leavenworth (CT), Jose Toscano (CT), Jeffrey Boyle (DE), Brian McCarty (HI, IL), Michael Wheeler (ID), Danny Baran (IL), Debra Wilson (IL), Michael Dusza (IN), Steve Abarr (IA), Sharon Cathers (KS), Andrew Fisher (GA, MO), Doris Margoles (ME), Prinna Boudreau (MN), Danny David (MT), Boniface Mills (NE), Christopher Glaub (NE), Sabrina Malone (NH, TX), Aaron Taylor (NJ), Joe David Dennett (NM), Beth Rodgers (NM, VA), Hugo Barragan (NY), Sonia Diaz (NY, SC), Bruce Ginsberg (NY), Jeffrey Bartalo (NC), Deana King (NC), Rachel Hock (OH), Chad Wells (OK), Antonio Perez Bonano (PR), Diane Lamontagne

			(RI), Stephen Flannery (SC), Susan Bakaitis (TN), Jeffrey Kemp (TN), Sarah Claunch (TX), Paul Panzera (TX), Madaline Harbor (VA), Elizabeth Heilman (VA), Cameron Rose (VA), Jose Lopez (WA), and Robert Peebles (WA)
Negligent Misrepresentation (Count III)	Carry over result from Motion to Dismiss PIAC	Carry over result from Motion to Dismiss PIAC	Carry over result from Motion to Dismiss PIAC
Medical Monitoring (Count IV)	Not a recognized claim (states require manifest physical injury)	CT, CO, DE, MT, NH	Jill Leavenworth (CT), Jose Toscano (CT), Sylvia McDaniel (CO), Jim Wolff (CO), Jeffrey Boyle (DE), Danny David (MT), Sabrina Malone (NH, TX)
Products Liability- Design Defect (Count V)	Failure to allege manifest physical injury	AZ, AR, CO, CT, DE, GA, HI, ID, IL, IN, IA, KS, ME, MN, MT, NE, NH, NJ, NM, NY, NC, OH, OK, OR, PR, RI, SC, TN, TX, VA, WA	Sean Purdy (AZ), Russell Autry (AZ), Patrick Nielson (CA, OR), Sylvia McDaniel (CO), Jim Wolff (CO), Jill Leavenworth (CT), Jose Toscano (CT), Jeffrey Boyle (DE), Brian McCarty (HI, IL), Michael Wheeler (ID), Danny Baran (IL), Debra Wilson (IL), Michael Dusza (IN), Steve Abarr (IA), Sharon Cathers (KS), Andrew Fisher (GA, MO), Doris Margoles (ME), Prinna Boudreau (MN), Danny David (MT), Boniface Mills (NE), Christopher Glaub (NE), Sabrina Malone (NH, TX), Aaron Taylor (NJ), Joe David Dennett (NM), Beth Rodgers (NM, VA), Hugo Barragan (NY), Sonia Diaz (NY, SC), Bruce Ginsberg (NY), Jeffrey Bartalo (NC), Deana King (NC), Rachel Hock (OH), Chad Wells (OK), Antonio Perez Bonano (PR), Diane Lamontagne (RI), Stephen Flannery (SC), Susan Bakaitis (TN), Jeffrey Kemp (TN), Sarah Claunch (TX), Paul Panzera (TX), Madaline Harbor (VA),

Negligent Design (Count VI)	Failure to allege manifest physical injury	AZ, AR, CO, CT, DE, GA, HI, ID, IL, IN, IA, KS, ME, MN, MT, NE, NH, NJ, NM, NY, NC, OH, OK, OR, PR, RI, SC, TN, TX, VA, WA	Elizabeth Heilman (VA), Cameron Rose (VA), Jose Lopez (WA), and Robert Peebles (WA) Sean Purdy (AZ), Russell Autry (AZ), Patrick Nielson (CA, OR), Sylvia McDaniel (CO), Jim Wolff (CO), Jill Leavenworth (CT), Jose Toscano (CT), Jeffrey Boyle (DE), Brian McCarty (HI, IL), Michael Wheeler (ID), Danny Baran (IL), Debra Wilson (IL), Michael Dusza (IN), Steve Abarr (IA), Sharon Cathers (KS), Andrew Fisher (GA, MO), Doris Margoles (ME), Prinna Boudreau (MN), Danny David (MT), Boniface Mills (NE), Christopher Glaub (NE), Sabrina Malone (NH, TX), Aaron Taylor (NJ), Joe David Dennett (NM), Beth Rodgers (NM, VA), Hugo Barragan (NY), Sonia Diaz (NY, SC), Bruce Ginsberg (NY), Jeffrey Bartalo (NC), Deana King (NC), Rachel Hock (OH), Chad Wells (OK), Antonio Perez Bonano (PR), Diane Lamontagne (RI), Stephen Flannery (SC), Susan Bakaitis (TN), Jeffrey Kemp (TN), Sarah Claunch (TX), Paul Panzera (TX), Madaline Harbor (VA), Elizabeth Heilman (VA), Cameron Rose (VA), Jose Lopez (WA), and Robert Peebles (WA)
Strict Liability – Failure to Warn (Count VII)	Failure to allege manifest physical injury	AZ, AR, CO, CT, DE, GA, HI, ID, IL, IN, IA, KS, ME, MN, MT, NE, NH, NJ, NM, NY, NC, OH, OK, OR, PR, RI, SC, TN, TX, VA, WA	Sean Purdy (AZ), Russell Autry (AZ), Patrick Nielson (CA, OR), Sylvia McDaniel (CO), Jim Wolff (CO), Jill Leavenworth (CT), Jose Toscano (CT), Jeffrey Boyle (DE), Brian McCarty (HI, IL), Michael Wheeler (ID), Danny Baran (IL), Debra Wilson (IL), Michael Dusza (IN), Steve Abarr (IA), Sharon Cathers (KS), Andrew Fisher (GA, MO), Doris

			Margoles (ME), Prinna Boudreau (MN), Danny David (MT), Boniface Mills (NE), Christopher Glaub (NE), Sabrina Malone (NH, TX), Aaron Taylor (NJ), Joe David Dennett (NM), Beth Rodgers (NM, VA), Hugo Barragan (NY), Sonia Diaz (NY, SC), Bruce Ginsberg (NY), Jeffrey Bartalo (NC), Deana King (NC), Rachel Hock (OH), Chad Wells (OK), Antonio Perez Bonano (PR), Diane Lamontagne (RI), Stephen Flannery (SC), Susan Bakaitis (TN), Jeffrey Kemp (TN), Sarah Claunch (TX), Paul Panzera (TX), Madaline Harbor (VA), Elizabeth Heilman (VA),
			Cameron Rose (VA), Jose Lopez (WA), and Robert Peebles (WA) Sean Purdy (AZ), Russell Autry
Negligent Failure to Warn (Count VIII)	Failure to allege manifest physical injury	AZ, AR, CO, CT, DE, GA, HI, ID, IL, IN, IA, KS, ME, MN, MT, NE, NH, NJ, NM, NY, NC, OH, OK, OR, PR, RI, SC, TN, TX, VA, WA	Sean Purdy (AZ), Russell Autry (AZ), Patrick Nielson (CA, OR), Sylvia McDaniel (CO), Jim Wolff (CO), Jill Leavenworth (CT), Jose Toscano (CT), Jeffrey Boyle (DE), Brian McCarty(HI, IL), Michael Wheeler (ID), Danny Baran (IL), Debra Wilson (IL), Michael Dusza (IN), Steve Abarr (IA), Sharon Cathers (KS), Andrew Fisher (GA, MO), Doris Margoles (ME), Prinna Boudreau (MN), Danny David (MT), Boniface Mills (NE), Christopher Glaub (NE), Sabrina Malone (NH, TX), Aaron Taylor (NJ), Joe David Dennett (NM), Beth Rodgers (NM, VA), Hugo Barragan (NY), Sonia Diaz (NY, SC), Bruce Ginsberg (NY), Jeffrey Bartalo (NC), Deana King (NC), Rachel Hock (OH), Chad Wells (OK), Antonio Perez Bonano (PR), Diane Lamontagne (RI), Stephen Flannery (SC),

Negligent Recall / Negligent Failure to Recall (Count IX)	Failure to allege manifest physical injury	AZ, AR, CO, CT, DE, GA, HI, ID, IL, IN, IA, KS, ME, MN, MT, NE, NH, NJ, NM, NY, NC, OH, OK, OR, PR, RI, SC, TN, TX, VA, WA	Susan Bakaitis (TN), Jeffrey Kemp (TN), Sarah Claunch (TX), Paul Panzera (TX), Madaline Harbor (VA), Elizabeth Heilman (VA), Cameron Rose (VA), Jose Lopez (WA), and Robert Peebles (WA) Sean Purdy (AZ), Russell Autry (AZ), Patrick Nielson (CA, OR), Sylvia McDaniel (CO), Jim Wolff (CO), Jill Leavenworth (CT), Jose Toscano (CT), Jeffrey Boyle (DE), Brian McCarty (HI, IL), Michael Wheeler (ID), Danny Baran (IL), Debra Wilson (IL), Michael Dusza (IN), Steve Abarr (IA), Sharon Cathers (KS), Andrew Fisher (GA, MO), Doris Margoles (ME), Prinna Boudreau (MN), Danny David (MT), Boniface Mills (NE), Christopher Glaub (NE), Sabrina Malone (NH, TX), Aaron Taylor (NJ), Joe David Dennett (NM), Beth Rodgers (NM, VA), Hugo Barragan (NY), Sonia Diaz (NY, SC), Bruce Ginsberg (NY), Jeffrey Bartalo (NC), Deana King (NC), Rachel Hock (OH), Chad Wells (OK), Antonio Perez Bonano (PR), Diane Lamontagne (RI), Stephen Flannery (SC), Susan Bakaitis (TN), Jeffrey Kemp (TN), Sarah Claunch (TX), Paul Panzera (TX), Madaline Harbor (VA), Elizabeth Heilman (VA)
			Elizabeth Heilman (VA), Cameron Rose (VA), Jose Lopez (WA), and Robert Peebles (WA)
Breach of Implied Warranty of Merchantability (Count X)	Failure to allege manifest physical injury	All States	All Plaintiffs
Breach of Implied Warranty of Usability (Count XI)	Failure to allege manifest physical injury	All States	All Plaintiffs

Breach of Express Warranty (Count XII)	Failure to allege manifest physical injury; consequential damage disclaimer in express warranty	All States	All Plaintiffs
Fraud (Count XIII)	Failure to allege fraud with particularity under Rule 9(b)	All States	All Plaintiffs
State Product Liability Acts (Count XIV)	Failure to allege manifest physical injury	All alleged states (CT, IN, KS, NJ, OH, TN, WA)	Aaron Taylor (NJ), Sylvia McDaniel (CO), Jim Wolff (CO), Jill Leavenworth (CT), Jose Toscano (CT), Michael Dusza (IN), Sharon Cathers (KS), Rachel Hock (OH), Susan Bakaitis (TN), Jeffrey Kemp (TN), Jose Lopez (WA), and Robert Peebles (WA)

REMAINING CLAIMS		
Claim	States Plaintiffs Asserting Claims Under Laws of These	
		States
Negligence (Count I)	CA, D.C., FL, MD, MO, NV, PA, UT, VT, WV	Paul Bailey (CA), Christine DiJohn (CA), Patrick Nielson (CA, OR), Patricia Ragland (D.C.), Tara Fields (FL), Dennis Morris (FL), Randy Paris (FL), Andrew Fisher (GA, MO), Wilbert Cotton (MD), Quinton Goodall (MD), Peter Bellotti (MA), John Young (MO), Elizabeth Lemus (NV), Arthur Hibbard (PA), Joseph Hoffman (PA), Marilyn Sweeney (PA), Martin Humphries (UT), David Martin (VT), Dennis Caling (WV), Brent Hamlin (WV)
Negligence Per Se (Count II)	CA, D.C., FL, MD, MO, NV, PA, UT, VT, WV	Paul Bailey (CA), Christine DiJohn (CA), Patrick Nielson (CA, OR), Patricia Ragland (D.C.), Tara Fields (FL), Dennis Morris (FL), Randy Paris (FL), Andrew Fisher (GA, MO), Wilbert Cotton (MD), Quinton Goodall (MD), Peter Bellotti (MA), John Young (MO), Elizabeth Lemus (NV), Arthur Hibbard (PA), Joseph Hoffman (PA), Marilyn Sweeney (PA), Martin Humphries (UT), David Martin (VT), Dennis Caling (WV), Brent Hamlin (WV)
Negligent Misrepresentation (Count III)	Carry over from PIAC	Carry over from motion to dismiss PIAC

Medical Monitoring (Count IV)	D.C., FL, MA, PA, UT, WV	Patricia Ragland (D.C.), Tara Fields (FL), Dennis Morris (FL), Randy Paris (FL), Peter Bellotti (MA), Arthur Hibbard (PA), Joseph Hoffman (PA), Marilyn Sweeney (PA), Martin Humphries (UT), Dennis Caling (WV), Brent Hamlin (WV)
Products Liability- Design Defect (Count V)	CA, D.C., FL, MD, MO, NV, PA, UT, VT, WV	Paul Bailey (CA), Christine DiJohn (CA), Patrick Nielson (CA, OR), Patricia Ragland (D.C.), Tara Fields (FL), Dennis Morris (FL), Randy Paris (FL), Andrew Fisher (GA, MO), Wilbert Cotton (MD), Quinton Goodall (MD), Peter Bellotti (MA), John Young (MO), Elizabeth Lemus (NV), Arthur Hibbard (PA), Joseph Hoffman (PA), Marilyn Sweeney (PA), Martin Humphries (UT), David Martin (VT), Dennis Caling (WV), Brent Hamlin (WV)
Negligent Design (Count VI)	CA, D.C., FL, MD, MO, NV, PA, UT, VT, WV	Paul Bailey (CA), Christine DiJohn (CA), Patrick Nielson (CA, OR), Patricia Ragland (D.C.), Tara Fields (FL), Dennis Morris (FL), Randy Paris (FL), Andrew Fisher (GA, MO), Wilbert Cotton (MD), Quinton Goodall (MD), Peter Bellotti (MA), John Young (MO), Elizabeth Lemus (NV), Arthur Hibbard (PA), Joseph Hoffman (PA), Marilyn Sweeney (PA), Martin Humphries (UT), David Martin (VT), Dennis Caling (WV), Brent Hamlin (WV)
Strict Liability – Failure to Warn (Count VII)	CA, D.C., FL, MD, MO, NV, PA, UT, VT, WV	Paul Bailey (CA), Christine DiJohn (CA), Patrick Nielson (CA, OR), Patricia Ragland (D.C.), Tara Fields (FL), Dennis Morris (FL), Randy Paris (FL), Andrew Fisher (GA, MO), Wilbert Cotton (MD), Quinton Goodall (MD), Peter Bellotti (MA), John Young (MO), Elizabeth Lemus (NV), Arthur Hibbard (PA), Joseph Hoffman (PA), Marilyn Sweeney (PA), Martin Humphries (UT), David Martin (VT), Dennis Caling (WV), Brent Hamlin (WV)
Negligent Failure to Warn (Count VIII)	CA, D.C., FL, MD, MO, NV, PA, UT, VT, WV	Paul Bailey (CA), Christine DiJohn (CA), Patrick Nielson (CA, OR), Patricia Ragland (D.C.), Tara Fields (FL), Dennis Morris (FL), Randy Paris (FL), Andrew Fisher (GA, MO), Wilbert Cotton (MD), Quinton Goodall (MD), Peter Bellotti (MA), John Young (MO), Elizabeth Lemus (NV), Arthur Hibbard (PA), Joseph Hoffman (PA), Marilyn Sweeney (PA), Martin Humphries (UT), David Martin (VT), Dennis Caling (WV), Brent Hamlin (WV)
Negligent Recall / Negligent Failure to Recall (Count IX)	CA, D.C., FL, MD, MO, NV, PA, UT, VT, WV	Paul Bailey (CA), Christine DiJohn (CA), Patrick Nielson (CA, OR), Patricia Ragland (D.C.), Tara Fields (FL), Dennis Morris (FL), Randy Paris (FL), Andrew Fisher (GA, MO), Wilbert Cotton (MD), Quinton Goodall (MD), Peter Bellotti (MA), John

		Young (MO), Elizabeth Lemus (NV), Arthur Hibbard (PA), Joseph Hoffman (PA), Marilyn Sweeney (PA), Martin Humphries (UT), David Martin (VT), Dennis Caling (WV), Brent Hamlin (WV)
Declaratory Judgment ²¹	All States	All Plaintiffs

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For the purposes of this roadmap for dismissal, Respironics has included Plaintiffs' declaratory judgment claim, based on the District Court's observation in the February 14, 2024 Memorandum Opinion that "at this stage of the case, the declaratory judgment claim appears plausible." ECF 2521, at 18. Respironics respectfully disagrees with that conclusion; it does not waive, and expressly preserves, its argument that Plaintiffs' declaratory judgment claim self-evidently fails as a matter law. Plaintiffs seek a declaration that "Philips is liable and responsible for the introduction of the [alleged emissions] into Plaintiffs' and Class members' bodies." MMSAC ¶ 739. That is not a claim for relief under the Declaratory Judgment Act. "Declaratory judgments are not meant simply to proclaim that one party is liable to another." *Andela v. Admin. Off. of U.S. Cts.*, 569 F. App'x 80, 83 (3d Cir. 2014) (affirming dismissal of declaratory judgment claim). No reasoning has yet been articulated, at any stage of either the motion to dismiss briefing or briefing on the parties' objections to the original R&R, explaining why Plaintiffs' declaratory judgment claim should not be dismissed.

Dated: April 10, 2024 Respectfully Submitted,

/s/ John P. Lavelle, Jr.

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Counsel for Defendant Philips RS North America LLC

CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2024, the foregoing document was electronically filed with the Clerk of the Court and served upon counsel of record through the Court's ECF system.

/s/ John P. Lavelle, Jr.
John P. Lavelle, Jr.